Dispatch

Health and Welfare Canada

Santé et Bien-être social Canada

NO
DATE INDEX (Revised)
January, 1974

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F.D.D. dispatch

Educational Services, Food and Drug Directorate
Department of National Health and Welfare, Ottawa

No. 17

Date November 1971

FOOD STANDARDS

For certain foods, criteria for composition and quality have been developed and these products must meet a standard defined in the Food and Drug Regulations.

Types of Standards:

Most of today's standards are for basic or staple foods such as bread, milk, cheese, tea, coffee, ice cream, shortening, meat, sugar, fish, poultry, canned fruits and vegetables.

Food standards usually fall into one of the following three categories:

1. Standard of Identity Such a standard merely defines the product. For example, the standard for cocoa beans reads: *"Cocoa Beans shall be the seed of Theobroma cacao L., or a closely related species."*
2. Standard of Composition This type of standard may either list ingredients a product must or may contain; or it may indicate analytical requirements (such as moisture, fat, ash and protein) which must be met; or it may do both.

   The Tomato Catsup standard is an example of a standard of composition which lists ingredients which must or may be used. This standard appears in the Food and Drug Regulations as follows:

   "Tomato Catsup, Catsup or products whose common names are variants of the word Catsup

   (a) shall be the heat processed product made from the juice of red-ripe tomatoes or sound tomato trimmings from which skins and seeds have been removed;

   (b) shall contain

   (i) vinegar,

   (ii) salt,

   (iii) seasoning, and

   (iv) sugar, invert sugar, glucose or dextrose, in dry or liquid form;

· food
· drugs
· cosmetics and medical devices

(c) may contain

(i) A Class 11 preservative, and

(ii) food colour."

No product sold as catsup may contain any other ingredient, however this standard does not apply to a product sold as tomato sauce or tomato condiment.

A standard of composition which lists both the ingredients and the analytical requirements is Apple Juice. It reads as follows:

"Apple Juice

(a) shall be the fruit juice obtained from apples;

(b) may contain a Class 11 preservative and vitamin C;

(c) shall have a specific gravity of not less than 1.041 and not more than 1.065 ($20^{o}C/20^{o}C$); and

(d) shall contain in 100 millilitres measured at a temperature of $20^{o}C$, not less than 0.24 gram and not more than 0.60 gram of ash which not less than 50 per cent shall be potassium carbonate."

3. Grade Standards Fresh fruit and vegetables are a type of product which lend themselves to standardization by quality or grade. This type of standard is handled by the Canada Department of Agriculture.

Purpose of Standards

Food standards have several functions. They protect the consumer from health hazards and fraud assuring them of a wholesome product. Because there is a food standard for catsup, you know that you are not buying water, coloured red, with thickeners added to give it body, but rather a wholesome tomato product. Thus, at the same time, standards benefit industry through the establishment of uniform rules protecting the ethical food processor from others who might attempt to present a cheaper product under the same name.

Problems of adulteration were present a century ago as evidenced by reports in 1877 which indicated that 80% of coffee being sold in Canada contained varying amounts of coffee mixed with chicory, roasted wheat, peas or beans and in one case, toasted bread crumbs.

At the turn of the century, Canada had only one food standard - for tea. Then in 1910 and 1911 came standards for milk, meat, grain products, and beverages, both alcoholic and non alcoholic. These were followed in 1912 by standards for edible vegetable oils, fruits, honey and flavouring extracts. Today, Food and Drug Regulations contain standards for approximately 300 food items.

Labelling of Foods

By regulation, unstandardized foods must carry a listing of ingredients on their labels in descending order of proportion. Presently, foods for which standards exist, standardized foods, are not required to have such a label declaration. The list of ingredients these foods must or may contain appears in the Food and Drug Regulations. However this distinction will eventually disappear as it is the objective of the Department of Consumer and Corporate Affairs and the Food and Drug Directorate to work towards a complete listing of ingredients on all food labels as far as practical.

Future Standards

Standards are not developed unnecessarily and may be changed when need for change becomes evident. Standards must be sufficiently flexible to provide for technological advances with regard to a particular food. At the same time as new foods arrive on our supermarket shelves, the need to write new standards follows.

When instant breakfasts were first proposed, the Food and Drug Directorate felt that if these new foods were to replace an otherwise nutritious breakfast, they should contribute a reasonable amount of certain nutrients.

The following regulation was prepared to ensure that those who use this product at breakfast would receive at least some nutrients in an adequate quantity.
"No person shall sell a product represented as ready breakfast or instant breakfast or by any similar designation unless each portion or serving of the product contains
(a) not less than 4.0 mg. iron;
(b) Vitamin A, thiamine, riboflavin, niacin or niacinamide and Vitamin C;
(c) a good dietary source of protein; and
(d) where consumed as directed, not less than 300 calories."

Microbiological requirements may appear more often in future food standards. Presently only a few standards consider microbiological aspects, one example being cottage cheese, which reads:
"No person shall sell cottage cheese or creamed cottage cheese that contains more than 10 coliform bacteria per gram as determined by the official method."

Summary

Food standards are formulated for the protection of the consumer. They serve a useful purpose for the consumer and the food processor. Food standards are not static but may and should be amended when they cease to serve their purpose.

New products constantly appearing on the market have caused a complete change in the types of food we eat and modern food distribution has increased the possibility of food borne illness outbreak through contamination of large quantities of food. Consequently future food standards may emphasize even to a greater extent than in the past, the nutritional and microbiological aspects while at the same time allowing the food processor sufficient latitude to encourage technological advances.

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Dispatch
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Educational Services, Food and Drug Directorate
Tunney's Pasture, Ottawa

Buy By Grade
Canada Department of Agriculture
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Publication may be obtained from Information Canada, 171 Slater Street, Ottawa
$5.00

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No. 19
Date April 1972

INTRODUCING THE HEALTH PROTECTION BRANCH

The name Food and Drug Directorate is disappearing from the organization of the Department of National Health and Welfare. A new Branch called Health Protection has been formed by the amalgamation of three former directorates:

Food and Drug
Environmental Health
Canadian Communicable Disease Centre

and two divisions

Epidemiology
Nutrition

Aims of the new Health Protection Branch are:

- to coordinate all activities pertaining to health protection under one umbrella in order to provide a more effective service to the public.
- to design programs to protect the public from a wide variety of hazards to health in the total environment such as those involved in: radiation, microbes, foods, drugs, cosmetics, toxic substances and medical devices.

By means of legislation; enforcement through inspection and compliance operations; research and consumer education services: the Food and Drug Directorate has been providing health protection for consumers in foods and drugs, since its formation as a unit in 1946. Although the familiar name, Food and Drug Directorate, is disappearing from our government vocabulary, the new Health Protection Branch will be functioning with the same aims and purposes but within a wider range of health protection activities.

To give you an idea of the scope of this new Branch, six main directorates are planned as outlined below with a central Epidemiology Service to serve all Health Branches of the Department.

FOODS

. research on nutrition, food composition, additives, bacterial contamination and other areas pertaining to food safety
. assessment of nutritional needs of the population
. investigation and evaluation of submissions from food manufacturers.

DRUGS

. research on drug quality, pharmacology and bioavailability
. control of manufacture and distribution of dangerous drugs
. programs concerned with the manufacturing, marketing and surveillance of drugs for use in man and animal.

ENVIRONMENTAL HEALTH

. research on health effects of the environment
. responsibilities encompassing surveillance and control of occupational hazards to health due to: Radiation
Air and Water
Techni-social environments.

LABORATORY CENTRE FOR DISEASE CONTROL

. provision of national reference laboratory services in the control of communicable and other diseases
. assessment of the safety and effectiveness of medical devices
. licensing authority over biological drugs such as antibiotics, vaccines and immunological products
. surveillance of sources of diseases carried by animals or insects and of their transmission to man.

ADMINISTRATION

. a centralized administration to service all units in the Health Protection Branch
. coordination and care of all animal research facilities in the Branch .

FIELD OPERATIONS

. this unit will in the main carry out the enforcement and inspection programs of the former Bureau of Operations of the Food and Drug Directorate.
. Educational Services will continue its communications link between the consuming public and the Health Protection Branch .

The new organization means Educational Services will have additional responsibilities and will expand services to provide information to the consumer and educator on the broad range of topics of interest to the entire Health Protection Branch.

Our Regional Consultants will also enlarge their areas of concern to encompass all elements of the Health Protection Branch. Their addresses are listed below.

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NO 21
DATE September, 1972

HEALTH PROTECTION BRANCH — FOOD PLANT INSPECTION

The main objective of Food Inspection activities of the Health Protection Branch is to prevent health hazards in the food supply, through enforcement of the Food and Drugs Act and Regulations. Through its five regional and 24 district offices, the staff of the Field Operations Directorate maintains an extensive surveillance of both imported and domestic foods.

This Dispatch will focus on the consumer protection work of the food plant inspection specialist whose job is to scientifically evaluate food plants for compliance with the health protection laws. Two basic aims of his work are:

- to promote careful manufacturing practices and encourage good quality control procedures as a means of providing food safe from health hazards.
- to uncover infractions of the Food and Drugs Act or Regulations and evaluate any health hazards in the food plant.

Science applied to enforcing consumer protection laws for food

To keep up with continuous strides in food technology and to keep a watchful eye on the flood of new foods which continues to pour into the market is a challenging and important job. Food inspectors must be university graduates in food science, chemistry or microbiology. From specialized experience and on—the—job training in the complex duties of a food plant inspection specialist, they develop an insight into food processing principles and become competent in detecting potential hazards.

Food protection legislation is embodied in the Food and Drugs Act. In essence the Act prohibits the sale of food manufactured under unsanitary conditions or containing harmful substances, both potential problems to consumer health.

In the Act "unsanitary conditions" mean such circumstances which might contaminate a food with dirt or filth or render the food injurious to health. Regulations accompanying the Act control the use of additives, food enrichment, special dietary foods and other food ingredients. Regulations are modified or new ones added to meet changes in food technology and also to regulate new areas "of concern", e.g. bacteriological standards.

The legislation also provides authority under which the inspector operates and is the basis for assessing food manufacturing practices. The Act gives him authority to enter a premise for inspection, to take photos, to examine records and to make copies of documents or to obtain other necessary evidence.

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What does the inspector look for?

In order to measure compliance with the Act and Regulations, and thus identify and control health hazards posed by food plants, the Health Protection Branch inspectors approach the food industry on a priority basis in line with predefined health hazards. Some examples of what inspectors look for follow:

Infective and toxic pathogens — this refers to the hazards associated with contamination from microorganisms such as salmonella, staphylococci and botulinum.

Fungal contamination — the contamination caused by moulds in certain foods such as cereals and nuts.

Pesticides — Are there excessive residues on foods? The regulations specify the type of food a pesticide can be used on and based on toxicological research the maximum amount of residue permitted on it.

Trace elements — Are there any hazards from excessive amounts of contaminants such as mercury, lead or cadmium?

Additives — Are they food grade and used according to regulations, i.e. used within the limits prescribed in terms of product, purpose and quantity?

Special Dietary Foods — designed for special diets such as low sodium or carbohydrate reduced. The formula and manufacturing procedures are evaluated for uniformity since variations from formula could be a health hazard.

In conducting a plant inspection the food inspector's objective is to follow the flow of food through the processing lines, taking notes of conditions and practices. He requests responsible plant personnel to be present during the entire inspection so that any problems can be discussed as observed.

All factors in the plant operations are evaluated in relation to the defined health hazard. The inspector gives attention to storage facilities and practices, operations and processing steps, sanitation, equipment maintenance and design, formulation practice, use of food additives, personnel and quality control procedures and any other aspect considered significant as a possible product contaminator.

In processing practices, he observes in-plant receipt and handling of raw ingredients, intermediates and finished products. He examines raw material for evidence of microbial and chemical contamination and compliance with standards in the regulations. He may pry into records to check if written specifications are available and if the company follows them. He is also concerned with records of testing procedures.

He will look for possible hazards in product flow. How carefully do supervisors monitor controls — cooking times, temperatures, humidity and pressure conditions? Are there any undue delays in going from one process to another which might be a health hazard? He investigates processing aids, formulations in relation to labelling declarations such as in special dietary foods, food enrichment and additives. In-plant storage practices are examined as well as the use and handling of returned goods. Transfer depots, dock sheds and trucks also come under his scrutiny.

Quality control important for a safe food supply

In food safety, quality control refers to all the precautions which management takes on a routine basis to ensure safe products. This applies to both raw materials and the finished products. It takes in qualifications of quality control personnel and their role within the plant, outline of routine testing performed, standard controls exercised over raw, finished and returned goods, record of complaints, knowledge of Food and Drugs Act, coding schemes and system for possible recalls.

Analysis of food samples an integral part of inspection

As the inspector progresses through the plant he will also pick up samples for analysis. These may be raw ingredients, intermediate products, finished food items, bacterial swabs, scrapings and other exhibits. Samples are analyzed in the Health Protection Branch Laboratories and these results form part of the total report of the inspector on the food plant.

These are but a few of the items the inspector will concentrate on. At the end of the inspection, which may often take several days, he will discuss his findings with management and indicate any immediate health hazard conditions to be rectified. In cases of serious health hazards or persistent shortcomings which show management's lack of concern, or failure to remedy a situation, the inspector will take steps to affect whatever action is required, such as seizure of products or prosecution. The courts decide the penalty for proven violations. Records of convictions are published quarterly and are available to the public.

Although food plant inspection is a most important activity in the inspection service, other duties are performed in the interest of health hazard protection. Some examples are: the investigation of consumer complaints pertaining to health hazards in food; the provision of guidance to manufacturers in interpreting the Act and Regulations; the arrangement for seminars and workshops for certain segments of the industry, and the supervision of any recall of food which may be a potential hazard.

Other Federal Departments such as Consumer and Corporate Affairs, Fisheries Service of the Environment, and Agriculture, also contribute to bringing good quality and safe foods to the table of consumers. However, the overall health hazard aspect is the responsibility of Health and Welfare's Health Protection Branch.

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Government Publications

NO 22
DATE October, 1972

SAFETY IS FOR THE BIRDS

Poultry is a carrier of potentially harmful bacteria called salmonella. These are easily destroyed at the recommended cooking temperatures as determined by a meat thermometer.

How much do you know about the safe handling of poultry?

QUESTION: If you buy frozen poultry, is it safe to let it stand on the kitchen counter to thaw before cooking?

ANSWER: Yes, but only if the poultry is wrapped in a brown paper bag or covered with a towel; this prevents the outside of the poultry thawing faster and getting warm before the inside thaws.

Actually the safest way to thaw poultry is in the refrigerator or in cold water in a watertight bag or container.

It can also be cooked frozen, but THE COOKING PERIOD SHOULD BE ONE AND A HALF TIMES THE NORMAL. For example, at 325°F, a thawed or fresh 10-pound turkey requires 4 to 5 hours for roasting. A frozen 10-pound turkey would require 6 to 7½ hours.

QUESTION: You have a big, plump turkey or chicken for a festive occasion. You want to slow-cook it for an early dinner, so you stuff it the night before and refrigerate it at once. The next day you roast it thoroughly. Safe or unsafe?

ANSWER: It is unsafe to stuff the bird the night before because the stuffing cools slowly and it is a superb food for the bacteria to grow in. All poultry should be cooked as soon as it is stuffed.

To cook a stuffed bird, stuff it loosely to allow heat to penetrate more quickly throughout the stuffing. For safety's sake use a meat thermometer to determine the temperature in the centre of the stuffing - not just in the turkey meat - and the temperature must reach 165°F. If you have more stuffing than will go in the cavity, the stuffing should be put in a separate container and cooked until the centre temperature reaches 165 F.

QUESTION: Should a bird be refrozen if it begins to thaw? for instance, in the case of power failure or mechanical breakdown of the freezer.

ANSWER: If there are still some ice crystals in the food, it can be safely refrozen, but the texture and colour will likely deteriorate.

Cooked foods that have been frozen and thawed should not be refrozen; this could be dangerous.

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QUESTION: How long should uncooked fresh turkey be kept in the refrigerator?

ANSWER: Fresh turkey is very perishable and should be stored in the coldest part of the refrigerator. The store wrapping should be removed and the turkey covered loosely with waxed paper or aluminum foil. The giblets should be removed from the body cavity and stored separately as they spoil more rapidly than the rest of the bird. Poultry should be cooked within 2-3 days.

QUESTION: How long should thawed turkey be stored in the refrigerator?

ANSWER: It should be cooked within 24 hours.

QUESTION: Is low temperature cooking of stuffed and unstuffed turkey safe, e.g. cooking overnight slowly?

ANSWER: Cooking a **stuffed** turkey at less than 300°F oven temperature is not safe.

Cooking an **unstuffed** turkey at a lower temperature could be safe providing THE FINAL TEMPERATURE OF THE MEAT AS MEASURED BY A MEAT THERMOMETER, INSERTED INTO THE THICKEST PART OF THE THIGH MUSCLE IS AT LEAST 190°F. (Be sure the thermometer does not touch the bone.)

QUESTION: If I purchase from a caterer a cooked and stuffed turkey, how should it be stored and reheated?

ANSWER: If the turkey is delivered shortly before serving time, remove the stuffing and keep the turkey and stuffing hot (above 140°F) until ready to serve. Otherwise, remove the stuffing and refrigerate both turkey and stuffing until it's time for reheating. To reheat, cover the bird with aluminum foil and baste occasionally. Place in a 300-350°F oven and heat until the meat thermometer reaches a temperature of at least 140°F. Keep in mind the turkey may have been held in the danger zone for several hours during delivery.

DANGER ZONE. Tempratures between 40°F and 140°F. Bacteria causing foodborne illness can grow and multiply rapdily between these temperatures. Below 40°F bacteria do not grow well. Above 140°F most bacteria are quickly killed.

QUESTION: How long should cooked poultry be stored in the refrigerator?

ANSWER: Turkey should be quick-cooled for storage. In the case of big birds this is difficult unless the meat is removed from the carcass promptly. A cooked bird should not be left on the table or counter for more than 2 hours. To store leftovers, it's safest to remove the meat and make it into separate meal-sized packets. Then you can store these packets in a covered container, plastic bag or aluminum foil for 3-4 days. The stuffing should be removed and wrapped separately. The stuffing will keep only a day or two in the refrigerator. The cooked poultry can be stored up to one month in the freezer.

QUESTION: How long can leftover turkey be kept in casseroles?

ANSWER: Turkey should be kept only 1 or 2 days in any kind of casserole or sauce, e.g. turkey à la king. Casseroles should be refrigerated below 40°F, and reheated thoroughly to 140°F or above before serving. Sauces or dressings such as mayonnaise combined with poultry are especially poor bets for away-from-home lunches.

*CHART ON FREEZER STORAGE TIME**

Maximum storage times for satisactory quality

	Storage time (months)
Uncooked chicken and turkey (whole)	12
Uncooked giblets, poultry (cut up)	6
Cooked poultry (slices or pieces) covered with broth or gravey	3
Cooked poultry not covered with broth and gravy	1
Cooked poultry dishes	1-2
Fried chicken	2
Poultry meat sandwiches	3

*THAWING TIMES FOR POULTRY**

Poultry Weight POUNDS	Refrigerator HOURS (5 hr.lb.)	Cold Water HOURS (1 hr./lb.)	Room Temperature HOURS (1½ hr./lb.)
5	25 (1 day)	5	7½
10	50	10	15
15	75	15	22½ (1 day)
20	100 (4 days)	20	30

Courtesy *Canada Department of Agriculture

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"Poultry. How to Buy/How to Cook", Canada Department of Agriculture, available from Information Canada

Health and Welfare Canada
Santé et Bien-être social Canada

NO 23
DATE December, 1972

TO SUPPLEMENT OR NOT

Canadians purchase approximately 40 million dollars worth of vitamin and mineral products each year.

Perhaps you wonder

- why there are so many different products on the market.
- what are vitamins and minerals?
- if you or other members of your family need a vitamin and mineral supplement.

VITAMINS is a general term for a number of unrelated chemical substances (nutrients) occurring naturally in various foods. They are necessary for the normal functioning of the human body but are not manufactured by the body. An insufficient intake of vitamins may result in disease or deficiency states.

Vitamins were discovered and given alphabetical letters by scientists during the early part of this century. Today some vitamins are still commonly referred to by letter however as their chemical structures were determined they were assigned chemical names which are becoming better known.

The quantity of a vitamin present in a product is expressed as milligrams (mg.), micrograms (mcg.) or International Units (I.U.). The International Unit is a measurement of biological activity.

MINERALS occur naturally in foods. They too are necessary for the normal functioning of the body. The quantity of a mineral present in a drug is usually stated in milligrams (mg.).

Healthy Canadians who eat a variety of foods as recommended by Canada's Food Guide will obtain all the vitamins (with possibly the exception of vitamin D), minerals and other nutrients essential for their health and well-being. A well balanced diet can be selected from foods commonly available in Canada (see Table I for daily nutrient intakes as recommended by the Department of National Health and Welfare for moderately active Canadians.)

Vitamin D - most adults obtain enough of it from their seasonal outdoors exposure to sunshine. However people living in northern regions with limited sunshine, infants, growing children, pregnant and nursing women and elderly persons confined indoors can obtain their quota by consuming milk with added Vitamin D (see Dispatch #2). A vitamin D supplement may be necessary for persons in one of the above groups who are not using Vitamin D fortified milk.

Table II gives the food sources and functions of essential vitamins and minerals.

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Vitamin and mineral supplements may be required

- during growth spurts, pregnancy, lactation, illness when the appetite is poor, or where by choice, circumstance or dislike of certain food groups, a normal diet is not consumed
- by young people who take to the road. They would be well advised to pack a vitamin supplement in their knapsack to compensate for problems in selecting proper foods while travelling
- by those whose diets consist mainly of hot dogs, hamburgs, chips and soft drinks and who need supplementation to ensure adequate nutrient intake

by weight watchers on a low calorie reducing diet who may also find it difficult to maintain adequate nutrient intake while their amount of food is limited.

Vitamin and mineral supplements are classified as drugs and are governed by legal requirements set forth in the Food and Drugs Act and Regulations.

- These products must comply with the general requirements for drugs including purity, potency, satisfactory manufacturing facilities and controls, claims, labelling and advertising.
- In addition special regulations prohibit the use of testimonials in advertising for vitamin or mineral supplements or the giving of assurance or guarantees of any kind with respect to results obtainable from taking these products.
- Advertising guidelines for radio and television ads for children's vitamin products were brought into effect in June 1972. Their intent is to lessen the possibility of developing drug taking habits in young children and to prevent promotion or purchase of drug products on the basis of premiums offered or recommendation by well known personalities or cartoon characters rather than health considerations.
- The manufacturer must also determine the period of time that his product will contain the amount of vitamin(s) stated on the label (potency) and label the product with an expiry date which falls within this period.

Whenever you purchase a vitamin supplement

- check the expiry date on the label and if the product is out of date bring this to the attention of the pharmacist or clerk.
- buy a product with an expiry date sufficiently in the future so that you will have used up most of the quantity before the time has expired.
- and it is kept in your home under normal conditions and protected from excessive heat, light, air or moisture, it is not necessary to discard the contents as soon as the expiry date is reached. Most manufacturers ensure that their products will have full labelled potency for several months beyond the stated expiry date to compensate for any adverse storage conditions or handling which may take place somewhere along the distribution chain between manufacturer and consumer.

Other regulations specify minimum amounts of specific vitamins and minerals which must be incorporated in products containing them. This ensures that a product contains sufficient quantity of a nutrient to be useful as a supplement.

- Lower minimums are given for products recommended for use by children under six years of age.
- Prior to implementation of these regulations it was not uncommon to find products available listing a whole alphabet of vitamins and minerals, often present in quantities too minute to be of any significance and many of which had no known role in human nutrition.

TABLE I

Daily Nutrient Intakes Recommended for Moderately Active Canadians[1]

	Weight lbs.	Calories	Protein* g.	Calcium g.	Iron mg.	Vit. A I.U.	Vit. D I.U.	Vit. C mg.	Thiamine mg.	Riboflavin mg.	Niacin mg.
Males	158	2850	48	0.5	6	3700	-	30	0.9	1.4	9
Females	124	2400	39	0.5	10	3700	-	30	0.7	1.2	7
Females (pregnancy)	-	-	50-59	1.2-1.9	13-15	4200	400	40	0.85	1.45	8.5
Children (0-6 yrs.)	6-40	360-1700	7-20	0.5-0.7	5	1000	400	20	0.3-0.5	0.5-0.9	3-5
Children (7-12 yrs.)	40-77	2100-2500	24-30	1.0-1.2	5-12	1500-2000	400	30	0.7-0.8	1.1-1.3	7-8
Adolescents	-	-	39-47	.9-1.2	12	2700-3200	400	30	0.9-1.1	1.6-1.9	9-11

*Protein recommendation is based on the average normal Canadian diet. Vegetarian diets may require a higher protein content.

(1)Condensed from Dietary Standard for Canada, 1963, Canadian Bulletin on Nutrition, Vol. 6, No. 1, March, 1964 revised 1968 by Department of National Health and Welfare.

The regulations also specify maximum amounts

- in order to prevent the advertisement and indiscriminate sale of products with massive doses of vitamins on the premise that if a small quantity is beneficial the benefit is multiplied with an even greater quantity
- so that products intended for self-medication and usually purchased without a doctor's recommendation will not pose any hazard to health when taken as directed on the label.

However it is recognized that diseases or deficiency states do exist where higher intakes of specific vitamins may be necessary. Therefore the regulations permit the over-the-counter sale of products containing more than the maximum levels provided they are prominently labelled For Therapeutic Use Only.

Vitamin supplements carrying this cautionary statement should not be purchased by consumers unless they have been recommended or prescribed by their physicians

An excess can be harmful.

- Although excess intake of most vitamins is excreted in the urine it has been known for some time that any excess intake of Vitamins A, D, E and K will be stored in the body and not excreted.
- Recently high doses of Vitamin A and Vitamin D have been shown to be detrimental to health and useful only for treatment under the direction of a physician.
- For safety's sake the Health Protection Branch has now placed the sale of products containing Vitamin A in daily doses larger than 10,000 International Units and Vitamin D in daily doses larger than 1,000 International Units on prescription only basis.
- If you have been using such a product you will now find that your pharmacist will request a prescription from your physician before he can sell it to you.

Labelling regulations for vitamin and mineral drugs

- limit claims that can be made for certain nutrients and prohibit any claims for other nutrients which may be present in the product
- require a cautionary statement when a drug contains the mineral nutrient fluorine to the effect that if the drug is used in an area where the drinking water has a natural fluorine content in excess of 0.7 parts of fluoride ion per million parts of water or is artificially fluoridated, mottling of the tooth enamel of the user of the drug may result

Before making a decision to buy a vitamin and/or mineral supplement for yourself or your family assess your eating habits.

- Decide if your diet is well balanced and made up of a variety of foods. If so it is unlikely that you will need supplements. You may just be wasting your money if you purchase them.
- If you are already consuming a high quantity of Vitamin A or D in your diet because of unusual food preferences, dieting, or some other reason you may exceed healthful limits by adding a supplement and do more harm than good.
- If on the other hand it is evident that your normal diet is deficient in some nutrients it would be wise to add a vitamin and/or mineral supplement to your diet to insure adequate intake.
- As a precaution it is always wise to check with your physician before you take any drug, particularly if you are considering one of the higher dosage products.
- In the case of infants using commercially prepared infant formula do not add a vitamin supplement unless your doctor so directs. Infant formula contain the required amounts of vitamins and minerals and you will be giving an excess dose.

References

Rx Bulletin March 1972, p. 38
Rx Bulletin March 1971, p. 33

TABLE II

Sources and Functions of Nutrients in Food[1]

NUTRIENT	FUNCTIONS IN	SOURCES
Vitamin A	• Normal growth and formation of skeleton and teeth • Maintaining normal vision • Resisting infection by keeping skin and lining layer of body healthy • Normal reproduction and lactation	Dark green and yellow vegetables, yellow fruits, egg yolks, liver, butter, cream, whole milk, cheeses, fortified skim or 2% milk, fortified margarine.
B Vitamin Group Thiamine	• Releasing food energy from carbohydrates • Normal growth • Maintaining good appetite • Normal functions of the nervous system	Pork and pork products (including organ meats), dried legumes (peas, beans lentils), whole grain or enriched cereals, flours, bread, potatoes and pastas.
Riboflavin	• Normal growth and development • Maintaining good appetite and normal digestion • Helping to maintain healthy skin and eyes • Helping to maintain a normal nervous system • Releasing energy to body cells during metabolism	Milk and milk products (except butter), cheese, eggs, meats (particularly organ meats), salmon, leafy green vegetables, enriched cereals, flours, breads and pastas.
Niacin	• Normal growth and development • Maintaining normal function of the gastro-intestinal tract • Normal function of the nervous system	Meat (particularly organ meats), fish, poultry, enriched cereals, flours, breads and pastas, tomatoes, peas, potatoes, peanuts and peanut butter, milk, cheese and eggs.
Vitamin B6 (Pyridoxine)	• Protein and energy metabolism	Meat, liver, vegetables, whole grain cereals, eggs.
B12	• Maintenance of healthy blood	Liver, kidney, milk, meat.
Folic Acid	• Maintenance of healthy blood	Liver, kidney, mushroom, asparagus broccoli, lima beans, spinach, lemons, bananas, strawberries, cantaloupe.
Pantothenic Acid	• Energy metabolism	Liver, kidney, egg yolk, nuts, legumes.
Vitamin C (Ascorbic Acid)	• Maintaining healthy teeth and gums • Maintaining strong blood vessel walls • Helping to form and strengthen the cementing substance which holds body cells together	Orange, lemon, grapefuit, lime, tangerine and their juices, vitaminized apple juice, vitaminized fruit drinks, tomatoes and their juice, cantaloupe, strawberries, broccoli, cauliflower, brussel sprouts, cabbage (green) white potatoes, turnips.

[1] References

Handy Nutrition, Associated Milk Foundation of Canada

Cooper's Nutrition in Health and Disease, Mitchell, Rynbergen, Anderson, Dibble. 15th Edition Lippincott

Vitamin D	• Utilizing calcium and phosphorus in the development and maintenance of sound bones and teeth.	Vitamin D enriched milks (fluid, evaporated and powdered) Vitamin D enriched infant formula preparations Vitamin D enriched margarines Vitamin supplements or fish liver oils.
Vitamin E	• Protecting body's supplies of Vitamins A and C • Maintaining health of membranes by being an antioxidant • Blood cell formation	Vegetable oils, e.g. corn and soybean, wheat germ, margarine and whole wheat bread.
Vitamin K	• Normal clotting of blood	Green and yellow vegetables Synthesized by intestinal bacteria.
Calcium	• Forming strong bones and teeth and maintaining and repairing the skeleton • Maintaining muscle tone, normal heart beat and healthy nerve function • Aiding normal blood clotting	Milk (any type), ice cream, cheese (any type), yoghurt, canned salmon and sardines (with bones), broccoli, navy beans (dried), string beans, turnips, carrots, dried apricots, cantaloupe.
Phosphorus	• Forming strong bones and teeth and maintaining and repairing the skeleton • Facilitates absorption and transportation of nutrients • Regulates the release of energy.	Meat, fish, poultry, eggs, nuts, milk, cheese.
Iron	• Building hemoglobin in red blood cells to transport oxygen and carbon dioxide • Preventing nutritional anemia	Liver, red meats, egg yolks, dried beans, peas and lentils, green leafy vegetables, whole grain and enriched cereals, pre-cooked infant cereals, flours, bread and pastas.
Fluorine	• Prevention and control of dental caries • Prevention of osteoporosis	Drinking water (natural or fluoridated water supplies) sea fish, tea.
Iodine	• Proper functioning of the thyroid gland	Iodized salt.
Magnesium	• Formation of bone • Metabolism of calcium and phosphorus	Cocoa, nuts, whole grains, spinach, liver, clams, oysters, crabs.
Zinc, copper cobalt, manganese, chromium, molybdenum and selenium	• Known to be important but functions in human nutrition are not fully understood	The average Canadian diet would provide the required amount.

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DATE January, 1973

THE MARKETING OF A NEW DRUG

A question often raised by consumers is how does Health Protection Branch ensure that new drugs offered for sale in Canada are safe and effective for uses claimed by manufacturers.

Any drug which has not been sold in Canada for sufficient time and in sufficient quantity to satisfactorily establish its safety and effectiveness is defined as a New Drug by the Regulations of the Food and Drugs Act. This same definition also applies to any new **form** or **use** for a drug which is currently on the Canadian market.

Before marketing a New Drug, a manufacturer must file a New Drug Submission with the Health Protection Branch and receive acceptance of this Submission in the form of a Notice of Compliance signed by the Assistant Deputy Minister, Health Protection Branch. The Drug Advisory Bureau in Health Protection Branch carries out activities related to these regulations and is responsible for ensuring that therapeutic drugs available in Canada have been adequately tested to ensure their purity, efficacy, and safety and produced to satisfactory standards.

Research

Scientists in universities, government laboratories and pharmaceutical companies regularly screen or synthesize new compounds or modify existing ones in the search for new chemo-therapeutic agents. The most promising chemicals are in turn screened to determine their effects in living systems since any such activity may indicate a potential useful new drug.

However, an enormous amount of research and development is required to move from initial discovery to finished drug. It has been estimated that chemists create or isolate up to five thousand different substances in order to come up with one new marketable drug.

Let us follow an imaginary new drug "Compound N" through its journey from test tube to consumer.

After isolation and purification by chemists, initial screening tests are carried out with Compound N in tissue cultures or small animals to see if any physiological or behavioural changes occur. This indicates if the drug is therapeutically active.

Positive results are noted for Compound N and so preclinical animal studies are initiated.

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Preclinical Testing

With certain exceptions the Branch requires that animal tests be carried out in at least three mammalian species (one of the species used must be a non-rodent). The acute (single dose) lethal dosage is first determined. Then a series of tests using different dosage routes gives the lethal dosage range for several species and provides a basis for approximating a dose suitable for human use.

These preliminary animal tests indicate that Compound N is not so toxic that its use in humans would be impractical. At this stage more detailed animal experiments are undertaken in order to determine toxicity symptoms arising immediately upon administration of the drug or from prolonged use and any adverse effects upon reproduction. These studies require careful, round-the-clock observation and detailed organ and tissue studies at autopsy.

At the same time biochemists and pharmacologists obtain data on Compound N's absorption, distribution, metabolism, elimination and possible accumulation.

The preclinical animal studies for Compound N take several years to complete but indicate it can be administered safely to humans and the manufacturer applies to Health Protection Branch for permission to conduct a Clinical Pharmacology Trial under the direction of a qualified investigator.

This type of trial is usually carried out on healthy volunteers starting with a dosage much less than the predicted effective dosage and gradually increasing to that level.

This permits the spotting of any adverse or toxic symptoms at the lowest possible dosage and provides comparative data on the metabolism of the drug in man versus animals tested previously.

At the same time the manufacturer is assessing the proposed methods for large scale production.

- can it be purified adequately and economically?
- can outside contamination occur at any point during the manufacturing process?
- will it be difficult to produce a uniform product of consistent quality and effectiveness?
- what is the shelflife of the product?

Clinical Trials

Compound N passes this screening and the manufacturer is now ready to start a full scale clinical investigation. He files a Preclinical New Drug Submission with the Drug Advisory Bureau and requests permission to distribute the drug to qualified investigators for clinical testing in order to obtain the necessary evidence concerning the new drug's dosage, effectiveness and safety in humans.

The Preclinical Submission presents all the evidence available to date on Compound N and must contain

- the objectives of the proposed clinical testing
- the identifying name or mark of the new drug
- its chemical structure and source
- the results of investigations made to support the clinical use of the new drug including toxicity, pharmacology and biochemistry
- the contra-indications and precautions which are necessary and known from the above tests
- suggested treatment for an overdose of the new drug
- the methods, equipment, plant and controls used in the manufacture, processing and packaging of the new drug
- the tests applied to control the potency, purity and safety of the new drug
- the names and qualifications of all investigators to whom the drug is to be distributed and the names of institutions in which the investigations are to be carried out.

This submission is examined by the Drug Advisory Bureau. If it has been properly completed, complies with the regulations and provides substantial evidence in support of the objectives and safety of the proposed trials the manufacturer receives notice that he may use the drug in these trials.

When the new drug is distributed to the qualified investigators for clinical testing it must be labelled *Investigational Drug* and *To Be Used by Qualified Investigators Only*.

In turn, the qualified investigator using this drug must sign an agreement with the manufacturer stating that he will

- not permit the new drug to be used by any other person unless under his direction
- use the new drug only for the clinical investigation agreed upon
- report immediately to the manufacturer and if required, to the Health Protection Branch, all serious adverse reactions encountered
- account on request to the manufacture for all quantities of the new drug received.

The types of tests carried out at this stage with Compound N will involve those persons with the disease state or condition it is expected to treat. The drug's action will be compared to other drugs or methods of treatment used for the same condition or to a placebo. (Placebos are preparations similar in appearance to the drug being tested but contain no active drug.) Placebos will not of course be used where a patient's health could be jeopardized by failure to receive a therapeutic drug.

The test protocols selected are designed to give sound statistical evidence as to the characteristics and usefulness of the drug. They would include

- objective clinical measurement using the *double-blind* (neither patient nor investigator knows whether placebo, control or test substance has been given) or *single blind* (only the patient does not know which therapy he receives).
- extensive laboratory analysis of patient's blood, serum, urine, etc. to corroborate clinical observations and to determine how the drug functions in the patient who is ill as compared to the healthy volunteer first tested.

Later field trials may be carried out by physicians on suitable patients in their practice to gain a more accurate appraisal of the drug's effects in everyday use outside of the hospital setting.

The New Drug Submission

From these human clinical studies our new drug Compound N has proven itself of value as a therapeutic agent and the manufacturer is now ready to file a New Drug Submission with the Drug Advisory Bureau requesting permission to market the new drug.

The New Drug Submission is more extensive than the Preclinical Submission but contains additional information such as

- all the human data from the clinical trials including substantial evidence of clinical effectiveness for recommended use, safety for this use and adverse effects noted.
- results of any further animal studies carried out by the manufacturer.
- the name under which the drug will be sold, its proper or chemical name and its description.
- a quantitative list of all ingredients, their specifications and if required the names and addresses for manufacturers of these ingredients.
- draft copies of the product monograph, labels, package inserts, product brochures and file cards for the new drug including details of route of administration, dosage, therapeutic claims, and contra-indications and side effects.
- samples of the finished form of the new drug which will be offered for sale.

All submissions must be documented correctly when submitted to the Drug Advisory Bureau. A New Drug Submission often requires many volumes of data and information and comprises thousands of pages.

Review and Evaluation in the Drug Advisory Bureau

First the Submission Control Section screens the submission checking for completeness. If nothing is amiss one copy of the submission is sent to the Manufacturing Control Division and the other to the Medicine and Pharmacology Division since Compound N is for human use. New drugs for animal use are sent to the Veterinary Medicine Division. The

Manufacturing Control Division evaluates the submission with respect to such areas as

- proposed manufacturing processes
- quality control procedures to ensure purity, uniformity and stability of product
- ingredient specifications and controls including assay methodology
- suitability of packaging materials
- suitability of manufacturing facilities for production of the new drug
- establishment of proper or generic name for the new drug.

The copy which goes to Medicine and Pharmacology or Veterinary Medicine is reviewed by experienced evaluators with backgrounds in fields such as clinical medicine, and pharmacology. These Divisions are divided into sections of specialists each dealing with a certain class of drugs such as cardiovascular, central nervous system, anti-cancer, etc. They carry out a detailed study of the animal investigations, pharmacology work, toxicity and teratological studies and clinical trials to assess the advantages and disadvantages of the drug. Finally the wording of the Product Monograph is considered.

Evaluators look for answers to such questions as

- has the full spectrum of drug activity been determined?
- do the toxicity studies show that there is a sufficiently wide spread between the therapeutic and toxic doses to permit a considerable margin of safety in actual clinical use?
- what toxic effects were observed in animals and might there be similar adverse reactions in man?
- do the teratological studies suggest that the drug should not be used by pregnant women?
- is the risk/benefit ratio satisfactory and is it comparable to that of other drugs used for the same therapy?
- does the Product Monograph contain complete prescribing information and are the statements made in it supported by the experimental and clinical data in the New Drug Submission?

In addition to this intensive review of the submission evaluators may contact outside investigators who worked with the drug during its development and trials for further information or clarification.

New Drug Submissions are often not cleared at the first review. The manufacturer may be asked for additional animal or clinical work to further clarify any toxicity potential or effectiveness in specific conditions.

The Product Monograph is the official document for the drug and gives complete prescribing information. Three or four revisions may be necessary before it is acceptable to the Drug Advisory Bureau.

Finally when the New Drug Submission is satisfactory it is returned to Submission Control where labels are examined and documentation completed.

Notice of Compliance

The Notice of Compliance is now prepared for signature by the Assistant Deputy Minister, Health Protection Branch. The Notice of Compliance is a document which indicates that the Health Protection Branch has found the content of the New Drug Submission satisfactory and in compliance with the regulations.

- biological data supplied is acceptable and provides evidence of the safety and effectiveness of the new drug.
- the Product Monograph has been finalized.
- manufacturing specifications and procedures have been found satisfactory.
- labelling has been examined.

The Notice of Compliance for Compound N is received by the manufacturer and he can now, more than five years after Compound N was first discovered in his laboratory, place his new drug product on the Canadian market.

Once a new drug is on the market, controls do not cease. It may remain in New Drug Status for a number of years until the Drug Advisory Bureau is confident that sufficient additional information has

accumulated from its general use to release it from the rigid controls applied to new drugs.

While in New Drug Status the manufacturer must report any new information he receives either through his tests or from users concerning unexpected reactions to the drug such as side effects or failure to produce desired effect.

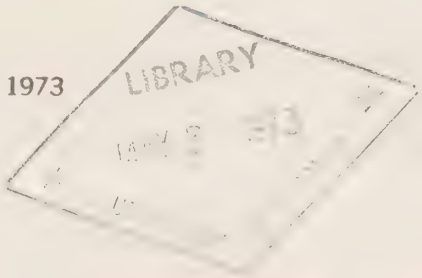
If Health Protection Branch determines at any time that it is in the interest of public health it may suspend the Notice of Compliance for a new drug and require that the drug be removed from the market.

References

Rx Bulletin Vol. 1, No. 5 p. 3, 1970
Rx Bulletin Vol. 2, No. 3 p. 36, 1971
Food and Drug Regulations, Part C, Division 8.

Health and Welfare Canada
Santé et Bien-être social Canada

NO DATE 25 February, 1973



TRUTH IN DRUG ADVERTISING

Drug advertising in Canada is controlled by legislation. Limitations on what may or may not be said in a commercial are under the jurisdiction of the Health Protection Branch of Health and Welfare Canada. Two federal government consumer protection acts, the Food and Drugs Act and Regulations and the Proprietary or Patent Medicine Act are the basis of restrictions.

The Food and Drugs Act prohibits the advertising and labelling of drugs in a "manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its value, quantity, composition or safety." The Patent Medicine Act is similar in content, it bans false, misleading or exaggerated statements in advertisements for patent medicines, and also prohibits any reference to the medicine as being a *cure* for an ailment. The role of the Health Protection Branch is to ensure that advertising practices do not contravene these acts.

Advertising as defined by the Food and Drugs Act "includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any drug, cosmetic or device." The definition applies to the media — radio and television, magazines and newspapers, also posters and street car ads; enclosures and circulars accompanying a product and direct mail. This bulletin is concerned only with the advertising of drugs to consumers in the media and will not discuss enclosures or labels which is a subject in itself covered by specific label regulations.

Why Protection in Drug Advertising?

Advertising is an accepted part of selling medicines in our competitive market place and is useful to consumers when it is informative and honest. Advertisements for drugs should be realistic in describing the condition to be treated and the effectiveness of the drug for the particular ailment. Unfortunately this has not always been the motivation. To offset the tendency to promote drugs by exploiting the desire of everyone for "well being", restrictions were imposed. Deceiving a consumer into buying a drug he doesn't really need by some emotional appeal, or misrepresenting the facts about a product is fraudulent and can be hazardous to health.

Early legislation

Patent Medicine Act.....

Laws to control drug advertising were passed by Parliament early in this century, in order to stop drug hucksters of the day from injuring public health. The Patent Medicine Act was passed in 1908 to control the sale of these drugs and the amended act of 1919 banned false misleading or exaggerated statements from all labels and in advertising. This

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was the beginning of a series of legislative controls towards truth in drug advertising

Food and Drugs Act.....

Legislation controlling drugs dates from 1875 and was concerned at first with adulteration. The early Adulteration Act was superseded by the Food and Drugs Act and in 1927 controls on the misbranding or false claims for drugs were added. Under its jurisdiction were drugs manufactured from pharmaceutical formulae and the products of an advancing medical science and therapeutic technology.

Added Legislation

As time went by and more drugs were made available to the public, it became necessary to further protect Canadians from health hazards and fraud in drug advertising by adding sections to the Food and Drugs Act and Regulations which explicitly designated diseases and conditions or products which could not be advertised to the public at any time. Some were specifically named in lists, called "Schedules". e.g.

Schedule A — A list of diseases, disorders or abnormal physical states:

- which can only be properly diagnosed and treated by a doctor.
- for which there are no known cures or treatment.
- for which self treatment is not considered safe.

This list includes such diseases as cancer, diabetes and heart conditions. (The complete schedule is listed at the end of this article.) It is subject to periodic review.

Schedule F — A list of drugs which can only be sold on prescription and which cannot be advertised to the general public at any time. Professional advertising to physicians, pharmacists, dentists and veterinarians is permitted.

Schedule G Controlled Drugs — , Barbiturates, amphetamines, pentazocine, (examples); like Schedule F they may only be advertised to health professionals (doctors, pharmacists, etc.).

Other controls restrict advertising of the following:

Therapeutic Vitamins — Vitamin supplements which are labelled "for therapeutic use only". These are high dosage vitamins intended for the treatment of established vitamin deficiencies and disease states, recommended to be taken only under the direction of a doctor.

Therapeutic Minerals — Products containing calcium, phosphorus, iron, fluorine, iodine, copper, or magnesium, intended for the treatment or prevention of a dietary deficiency, may be advertised within prescribed limits. No other minerals may be promoted to the public.

Stringent legislation controls minerals and vitamin advertising to prevent unlimited or exaggerated claims. It is considered misleading and fraudulent to promote self administered excesses of vitamins. The general philosophy for advertising control for both minerals and vitamin supplements is that they should not be portrayed as a necessary part of everyday living and should only be used when the diet is deficient for some reason. The regulations for minerals and vitamins prohibit:

- the use of testimonials to guarantee or assure results from taking vitamins or minerals
- any claims other than those listed in regulations where it may be stated, for

Vitamin C — it is a factor in the normal development and maintenance of bones, cartilage, teeth and gums.

Vitamin D — it is a factor in the normal development and maintenance of bones and teeth, especially in infancy and childhood.

Other vitamins — (on permitted list to be advertised) — it is a factor in the maintenance of good health.

Iron — this mineral is a factor in the prevention of iron deficiency.

Calcium, phosphorus or iron — these minerals are a factor in the maintenance of good health.

There are certain vitamins for which no claims may be made — This group includes Vitamin B_{12}, Vitamin E, Vitamin K and B_6

Advertisements for Children's Vitamins — Special Guidelines

Special guidelines for children's vitamins were issued by the Health Protection Branch in June 1972. They are designed to reduce pressures on parents to buy these products and to lessen the possibilities of establishing drug-taking habits, as a result of drug advertising. A main concern is the potential for children acquiring habits which could lead to more serious consequences as they grow older.

These guidelines state that ads must not:

- imply that all people need vitamin supplements.
- exaggerate expected benefits nor portray pill taking as a "fun thing" or the "grown-up" thing to do.
- depict children taking the vitamin preparations on their own.
- create pressures on children to urge parents to buy certain brand vitamins for special give-a-way offers.
- use nationally known persons such as movie stars, cartoon characters or athletes, in the direct presentation of ads.

Enforcement of Controls

Radio and TV Commercials

Drug commercials for radio and TV must be previewed and cleared by the Department of Health and Welfare to ensure that they do not contravene the Food and Drugs or Patent Medicine Acts. This is required under Section 11 of the Canadian Radio Television Commission Broadcasting Act. This Act also requires the script to be stamped with a CRTC registration number. The ads must be aired exactly as cleared and may be used for a year from the date of stamp. If any changes are made, the commercial must be resubmitted for review.

As a further control, the regulations require the station and network operator to keep a record of use for the approved continuity, showing name of product, advertiser or agent and number assigned. The inspectors of the Department of Consumer and Corporate Affairs regularly examine these records. Although a commercial may have a registration number, this does not imply any obligation for the broadcaster to use it. Final discretion to use a cleared ad and the time of airing is the prerogative of the station.

Magazines, newspapers

Print ads do not require pre-clearance review by the Health Protection Branch but a selection of popular English and French Canadian magazines and newspapers are monitored for any violations of the Acts. If copy does not conform with the regulations, the advertiser is asked to change it; charges can be laid and prosecution initiated in the courts for failure to comply. To be on the safe side some agencies send ads for pre-clearance review before they are printed.

The Drug Operations Division of the Health Protection Branch acts as a clearing house for reviewing ads. Some criteria for judging the acceptance of submissions, under the consumer protection legislation are as follows:

Can the drug be advertised to consumers? — A drug which does not fall into one of the prohibited classes may be advertised. Such a drug is generally intended for those conditions which can be self-diagnosed and self-treated, e.g. headache pills, cough medicines and cold remedies.

False advertising — Some examples of false statements which would not be acceptable:

- A drug commercial may say a product containing A.S.A. relieves rheumatic pain but it would not be acceptable if it stated that the preparation *cures* the rheumatic condition. There is no known absolute cure for rheumatism.
- An ad may state that internal analgesics may relieve ordinary headaches and the aches and pains associated with a cold. On the other hand, no claim may be made that it induces sleep, or relieves the pressures of daily living.
- There is no evidence to prove that the use of laxatives improves the complexion, clears skin eruptions, and produces bright eyes. Such a statement is therefore not acceptable in drug ads.
- A cough mixture may suppress a cough or relieve congestion. There is however, no drug which will stop or prevent a cold; therefore this claim cannot be made in a drug commercial.

Erroneous impressions or misleading statements

When a commercial uses words and phrases, scenarios or illustrations that could be misleading to the public, it will not be acceptable. The following illustrate potentially misleading situations:

- Endorsement by scientists, doctors or nurses, testimonials from users, or quotations from the media.
- Comparison with other products which exaggerate differences of little significance in terms of therapeutic effect.
- Use of comparative vague words such as better, richer, lower without reference to a comparable product.
- Implication that a drug is completely harmless and non toxic, since any drug can be harmful if taken in excess especially by young children.
- Use of the popular word "organic" to denote superiority. Most drugs are organic compounds by chemical definition so this is a meaningless word.
- Negative claims which infer that one product may be better than another because it does not contain a particular ingredient which may or may not be in other products.
- Scare advertisements which suggest that your health may suffer if a particular drug is not used.
- Visual Presentation or Illustration — Men and women in white clothing, hospital or medical clinic settings or impressive lab equipment used to create an atmosphere but having no connection with the product can give a false impression and would be rejected.

Proper Usage and Storage of Drugs

To keep the public mindful of the need for safe storage and proper use of drugs, objections would be taken to any advertising material which illustrated unsafe drug storage or any which encourages excessive drug taking. Examples of non acceptable situations would be:

- Visuals which showed drugs on night tables or in a drawer — safe storage means in an enclosed place **out of the reach of children.**
- A person taking a pill when half-awake — this could lead to taking a wrong drug.
- Any visual which leaves the impression that increasing drug dosage increases the efficiency of the drug.
- One which suggests that every unpleasant aspect of life can be relieved by taking a pill.

Ads directed to children are also in the list of non acceptable contexts. (see also, above, Vitamins for Children Ads).

Listen In

Advertising legislation and policy controls of the Health Protection Branch are periodically reviewed. New facts from scientific research or technological developments can change concepts and lead to changes in regulations in drug promotion. Increasing consumer sophistication and knowledge of drugs may indicate the need for more informative and health oriented commercials.

One further reminder — Advertising seen or heard in border areas on American television channels or radio stations does not come under Canadian controls. The same applies to U.S.A. publications. As American regulations are not the same as Canada's, some U.S. commercials would not comply with our laws, thus could not be aired on Canadian stations or appear in Canadian magazines. However, the Health Protection Branch cannot prevent commercials originating in the United States from being seen or heard in Canada.

SCHEDULE A

Alcoholism
Alopecia
Anxiety state
Appendicitis
Arteriosclerosis
Bladder disease
Cancer
Convulsions
Depression
Diabetes
Disease of the prostate
Disorder of menstrual flow
Dysentery
Edematous state
Epilepsy
Gall Bladder disease
Gangrene
Glaucoma
Gout
Heart disease
Hernia
Hypertension
Hypotension
Impetigo
Influenza
Kidney disease
Leukemia
Liver disease
Nausea and vomiting of pregnancy
Obesity
Pleurisy
Pneumonia
Poliomyelitis
Rheumatic fever
Rheumatoid arthritis
Scabies
Septicemia
Sexual impotence
Tetanus
Thyroid disease
Tuberculosis
Tumor
Ulcer of the Gastro-intestinal tract
Vaginitis
Venereal disease

References

Dispatch from Educational Services,
Health Protection Branch
Cosmetic or Drug No. 8.
Patent Medicines No. 14.
To Supplement or Not No. 23.

Cosmetic Pamphlet — Educational Services
Drugs Handle With Care — Educational Services

Health and Welfare Canada
Santé et Bien-être social Canada

NO 26
DATE March, 1973

AFLATOXIN ANALYSIS FOR CONSUMER PROTECTION

Moulds play an important role in foods. Some beneficial moulds produce products which enhance flavour such as the moulds used to make blue, Roquefort and Camembert cheeses.

Some moulds are undesirable because they contribute to food spoilage, making it necessary to discard food which has been held too long. Other undesirable consequences of moulds include food crop losses due to rusts and blights.

While there are many edible fungi, for years man has shunned toadstools and some related fungal species, rigorously excluding these harmful substances from his diet. Nature forms many poisonous products which we have learned not to eat, examples such as the berries of mistletoe, parts of many ornamental plants and common plants like the jack-in-the-pulpit, buttercup and hemlock.

Some strains of the mould *Aspergillus flavus* produce a group of toxic substances called aflatoxins. Aflatoxins are known to be formed by mould growth which may occur on certain foods stored under poor conditions. Specific foods which are particularly subject to this type of mould damage are edible nuts and nut products, especially peanuts and peanut products.

Aflatoxin undoubtedly has been a natural contaminant in specific foods since time immemorial. It is not something new, only our knowledge of it is new — a result of modern technology. Scientists have developed methods to measure its occurence in extremely small amounts (parts per billion).

Research has shown that aflatoxin is toxic to fish, birds and animals. Because of its potential hazard to health it is imperative that every possible precaution be taken to ensure that peanuts, peanut products and other susceptible foods are free of this substance. The Health Protection Branch has an active program to eliminate aflatoxin from foods sold in Canada.

Because of the popularity of peanuts and peanut products they are of special concern, and a program for monitoring and controlling these products has been developed.

Conditions favouring the growth of *Aspergillus flavus* occur in the tropical areas where peanuts are grown. Aflatoxin is produced fairly rapidly at temperatures above 68°F and a moisture content in nuts of 9% or more. When first harvested peanuts have a moisture content of 30%. However they are dried to 8% moisture and no toxin production occurs during transport and storage when low humidity and moisture contents are maintained.

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Industry is responsible for the quality of raw peanut shipments imported for processing. When the nuts reach the final processing stage, they are carefully sorted after roasting. This eliminates any toxin containing nuts at a stage when no more toxin can be produced. This sorting is the final step which insures a safe product. Toxin residues are found only in a small proportion of nuts and these are almost always damaged or discoloured. Besides manual sorting, peanuts can also be scanned by an "electric eye" or photo cell which compares their colour to reference colours. The machine is set to reject any discoloured nuts.

Health Protection Branch inspectors routinely inspect peanut processing plants to ensure that management establishes good manufacturing practices to eliminate aflatoxin from the finished product. The inspectors assess the plant quality control program pointing out specific weaknesses in manufacturing control.

The surveillance activity is centered around inspection and laboratory analysis of the finished product. Samples of peanut butter are taken regularly during plant inspections as well as from retail outlets. Enforcement action and product recall actions are taken on any lot of peanut products, reaching the market which violate the regulations. If the plant inspection indicates any aflatoxin risk, increased emphasis is placed on sampling the finished product.

The Health Protection Branch continually tests nut products other than peanuts. Any product available to the consumer containing aflatoxin above a carefully determined level is considered to be a potential health hazard and is rigorously rejected.

Through inspection and laboratory analysis at import, storage, manufacture and retail levels, foods are monitored for the presence of aflatoxin.

The Health Protection Branch is continuing to take every possible precaution to ensure that aflatoxin, a naturally occurring harmful mycotoxin is not present in Canadian foods.

Explanation of Terms — Associated with Mould Discussions

Toxin: poison

Mycotoxin: a generic term to describe those poisonous substances formed by moulds. Once formed, some mycotoxins remain even though the moulds may subsequently be killed by sterilization.

Aflatoxin: a mycotoxin. The toxic substance produced by some strains of the mould *Aspergillus flavus*.

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Health and Welfare Canada
Santé et Bien-être social Canada

NO 27
DATE July, 1973

THE QUAD PROGRAM

In May 1971, the Federal Department of Health announced the initiation of the Drug Quality Assessment Program (generally referred to as "Quad"). The first yearly compilation of the results of the Quad Program, covering the work done during 1972, was published in February 1973. The following series of questions and answers outlines the major features of this program.

Q. *What is the purpose of the Quad Program?*

A. The Quad Program is designed to provide information to pharmacists, medical practitioners and bulk purchasers of drugs. The information about drugs presently marketed, will enable members of the health professions to decide on the basis of scientific and technical facts the comparable drug products which may be prescribed or dispensed at reduced cost.

Q. *How can Quad benefit the consumer?*

A. The intention of the Quad Program is to assess the quality of drugs marketed in Canada and at the same time to reduce their price. At the retail level alone, the cost of prescription drugs is estimated to exceed $400 million per year. Drugs to be assessed by Quad represent $150 million of this figure.

Q. *How will drug costs be reduced?*

A. There are four principal elements comprising the program for each selected drug entity: chemical analysis, comprehensive evaluation of drug manufacturing and distributing facilities, assessment of clinical effectiveness, and publication of these data as well as the product cost to the pharmacist for various brands of the same drug. Referral to this published information by physicians, dentists and pharmacists will enable them to select high quality drugs at lower prices. Bulk purchasers of drugs such as Provincial governments may also achieve cost reduction through selective tendering for drugs based on Quad data.

Q. *What drugs are tested and how are they selected?*

A. When in full operation, the program will provide analytical data on all brands of the "top" 125 single component drugs, manufactured by more than one company. Priorities within this group are established by considering four factors: the importance of the drug's medical use, its sales volume, the precision of the dosage required, and the stability of the product and the risk of contaminants.

Q. *What tests are actually conducted on the drugs?*

A. Each drug is analysed for potency, purity, content uniformity, and disintegration time as required by the manufacturer's labelled standard.

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In addition, when considered important, bioavailability determinations are conducted. This is an indirect measure of clinical effectiveness based on measurement of blood levels and/or urinary excretion of the drug obtained from human subjects who have taken the drug.

Q. *What happens if a drug fails to meet one or more of the established test criteria?*

A. Appropriate action is taken depending on the health hazard to the consumer in terms of safety and effectiveness of the drug product. This could result in a warning being given to the manufacturer, or the seizure of all stocks of that lot at his or the distributors premises, or the seriousness of the defect may be such that the product has to be recalled from the market. Once any immediate hazard to the Canadian public has been removed, an investigation is conducted at the site of manufacture to determine the cause(s) of the failed test(s) and the measures required to prevent a recurrence. Enforcement action such as prosecution would be initiated if warranted.

Q. *Has much work been done so far?*

A. By the end of 1972, 24 drug entities or approximately 400 drug products had been analyzed. A total of 100 drugs or 1,500 individual products are expected to be tested in 1973. Thereafter, all brands of the "top" 125 single component drugs, manufactured and sold by more than one company, will be assessed each year.

Q. *Who is responsible for doing the analysis?*

A. Much of the analytical work is done at the newly constructed drug quality monitoring laboratory in the Toronto Regional Laboratory of the Health Protection Branch, Health and Welfare Canada. This laboratory is equipped for large scale analyses by automated methods and when fully operational will conduct nearly 90,000 tests per year. The bioavailability studies on drugs with critical dosage requirements are conducted at the HPB Drug Research Laboratories in Ottawa or on contract by non-governmental medical experts. This program of government testing is the first such program in the world and has made Canada a leader in this field.

Q. *Who is responsible for gathering the price information?*

A. The compilation of price data is the responsibility of the Consumer Research Branch of the Department of Consumer and Corporate Affairs in cooperation with the pharmaceutical manufacturers.

The prices of drugs listed, however, are not the prices a consumer will pay when a prescription is filled. The prescription price to the consumer is composed of two parts — the cost of the prescription ingredients (the Quad price list) plus the fee charged by the pharmacist for his professional services, overhead and facilities costs.

Q *Is this the first time that the Government has systematically analyzed the quality of drugs and conducted evaluations of manufacturing facilities?*

A. **No.** Mandatory plant inspection and analytical programs have been conducted for many years but most of the information gathered remained confidential. Whereas other inspection programs cover a manufacturer's total operation, the Quad evaluation assesses the capability to manufacture and distribute individual drug entities. For legal reasons, the plant evaluation phase of the Quad Program is on a voluntary basis since manufacturers must give their consent for the release of this information. The drug analysis phase, however, is mandatory and is conducted solely on priorities established by the Health Protection Branch.

Q. *Are the results of the Quad Program available to the public?*

A. **Yes.** The results of the Quad Program are published yearly, in a supplement to the Rx Bulletin, the drug information publication of the Health Protection Branch. All provinces, health agencies, hospitals, and members of the health professions receive reference copies. The general

public can order the Quad supplement through Information Canada bookstores.

Q. *What can the public do to assist in reducing the cost of drugs?*

A. The success of the Drug Quality Assessment Program is dependent on utilization of the published information by the health professions. Talk to your physician and pharmacist and encourage them to use the Quad data when prescribing drugs and dispensing prescriptions for you. The money saved is yours.

GLOSSARY

In order to appreciate the preceding information describing the tests required for quality assessment of pharmaceutical products (drugs), it is necessary to understand certain terminology.

1. **Excipient:** In many instances the major part of a tablet or the content of a capsule consists of inert, innocuous materials called excipients. These excipients have no medicinal effect but rather act as a vehicle to carry the drug chemical to the site of action within the patient in an acceptable form. Many modern drugs are so powerful that the required therapeutic dose is very small. It would be almost impossible to deliver an accurate amount of drug without this means. A tablet containing only the drug might be microscopic in size.
2. **Standard:** In Canada drugs must be manufactured to meet either an official compendial standard such as those listed in Schedule B to the Food and Drugs Act (e.g. British Pharmacopeia, United States Pharmacopeia), or the manufacturer's established "house" standard for that particular drug. A "house" standard must be equal to or more stringent than any compendial standard with respect to potency and purity.
3. **Potency:** The amount of active drug in any one tablet, capsule or 5 ml. teaspoonful of a syrup etc. is the potency. It can be expressed in milligrams (mg), grains (gr) or International Units (I.U.).
   e.g. 5 gr Acetylsalicylic acid.
4. **Purity:** All components of a pharmaceutical (drug) i.e. the active drug and excipients, must be pure and not contaminated with other chemicals or extraneous matter.
5. **Weight Variation:** The overall weights of individual tablets or capsules (active drug plus excipients) should be similar and are sample tested by weighing on a balance. This test helps ensure that the patient receives the same amount of active drug from all tablets or capsules he takes.
6. **Content Uniformity:** The variation in the quantity of drug in each of the tablets and capsules in a particular manufactured lot must be minimal in order to ensure that the patient receives the same amount of active drug from all tablets or capsules he takes. The test is carried out by chemically analyzing each tablet or capsule for the amount of active drug it contains. This test is more discerning than the test for weight variation.
7. **Disintegration Time:** In order for a pharmaceutical product to benefit the patient, the active drug which it contains must first of all be released from the tablet or capsule into the stomach or intestine where it dissolves and then passes into the blood stream. Before the active drug can be released, it is necessary for the tablet or capsule to break up. The time required for disintegration must fall within prescribed limits and this is checked in the laboratory by slowly shaking the tablets or capsules with simulated gastric or intestinal fluids and recording the time it takes for complete disintegration of the capsule or tablet.

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NO 28
DATE October, 1973

PAIN RELIEVERS — FOR SELF MEDICATION

Analgesics or pain relievers are commonly used drugs in the home. They include a wide variety of drugs which have the ability to relieve pain in various degrees. A few preparations reduce fever (antipyretic) and some reduce inflammation (anti-inflammatory) as well. Brand names and different combinations of ingredients make up about 1000 different preparations.

While some pain relieving drugs are available only on prescription many can be sold directly over the counter and are purchased by consumers either at a pharmacy or at other outlets. This Dispatch will discuss the self-prescribed type of analgesics for internal use, intended for short term relief of minor symptoms such as headache, toothache, muscular aches and rheumatic pain.

HOW ARE CONSUMERS PROTECTED?

Drugs sold in Canada are controlled by three Federal consumer protection acts — The Food and Drugs Act and Regulations, the Narcotic Control Act and the Proprietary or Patent Medicine Act (PPM). Controls are applied in areas of manufacturing, advertising, licensing and labelling. These laws administered by the Health Protection Branch, Health and Welfare Canada, are enacted so that Canadians may obtain drugs which are safe for their intended use and effective for the claimed purpose.

Label Regulations — For self administered medication, label information is of utmost importance for the consumer and should always be read and heeded. As well as product identification and address of manufacturer, the regulations for labelling require specific information in clear print including the following:

- list of medicinal ingredients (PPM drugs do not presently require complete listing — only the more active ingredients*)
- directions for use
- special directions for use (i.e. single dose and maximum dose) and conditions under which the drug should not be taken
- strength and dosage form of drug
- special warnings such as those on labels of products containing acetylsalicylic acid (ASA)**

Labels are checked by the Health Protection Branch to ensure that the claims made by the manufacturer are true and that recommended doses are correct for the intended use of the preparation, according to the Food and Drugs Act and Regulations. The labels of PPM drugs are checked before a Registration number is issued.

*See Dispatch No 14 — Patent Medicines
**See Dispatch No 5 — New Warning Labels on ASA Products

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DO WE USE TOO MANY?

Analgesics which can be sold without a doctor's prescription are intended to be bought and used with discretion. Good health can be threatened if these are used over long periods or in dosages larger than recommended on the label. Surveys in several countries have shown that some people take analgesics habitually without any good medical reason. According to Statistics Canada, 2 million pounds of acetylsalicylic acid were imported in 1972; enough to make 2 1/2 billion tablets or 125 tablets per person. This indicates either Canadians have many aches and pains or else some people are using too many pain relievers, perhaps for unnecessary or inappropriate reasons.

THE ACTION OF DRUGS IN THE BODY

Drugs are chemicals which can be formulated to affect a function or a part of the body. At the same time the human body is doing something to the drug. Normally the body metabolizes the drug — i.e., it breaks down the drug into chemical components which can be absorbed into the system and carried to the site in the body where the drug can produce the desired action. Then the body eliminates the drug. Normal metabolism requires adequate performance of organs of the body such as the liver, kidney and lungs. If a person cannot metabolise the drug because of the inability of the body to handle the chemicals for one reason or another, the drug may have a harmful effect instead of a beneficial one. If the misuse of analgesics disturbs the delicate balance of the body's chemistry the restoration of normal functions may be impeded and a hazard to health is created.

ADVERSE REACTION

All individuals do not react to medicines in the same way. Analgesics like other drugs can cause different sometimes undesirable effects than those expected. These undesirable effects could vary with a person's individual sensitivity to a particular analgesic preparation or ingredient in it or with the person's health condition at the time. Examples of some conditions which could modify the person's reaction to the pain reliever are: the presence of stomach ulcers, a special dietary program such as a low sodium one, the taking of anticoagulant drugs, and presence of asthma. It is safer for persons with any of these ailments to consult a physician before taking analgesics for self medication. If a person is sensitive to a particular ingredient or preparation, a pharmacist could help him in his selection as he is familiar with the ingredients in drugs and may suggest a suitable substitute.

COMMON INGREDIENTS USED IN ANALGESICS FOR SELF MEDICATION (See table listing preparations)

1. Acetylsalicylic Acid — ASA

ASA is the most common chemical in pain relievers and is available in many forms — plain, buffered (ingredients are added to counteract acidity), effervescent, in combination with other chemicals and in countless remedies.

Effects

- ASA relieves minor or less severe pain such as headaches, or rheumatic pain.
- it can reduce fever associated with the common cold but has no effect on the infection.

Permitted Dosages

- **Adults**

  Single dosage — one to three—5 grain tablets or 325mg to 975mg.

  Maximum daily dosage — nine—5 grain tablets or 2.925 grams.

In certain cases a physician may prescribe higher dosages for a special condition. However the dosage prescribed should never be exceeded.

ASA has been used for years with good results for pain relief but it should also be pointed out that it has been associated with such undesirable effects as:

- stomach distress, heartburn or indigestion,
- alteration in blood clotting factors — hence patients with bleeding disorders and those using anticoagulants should take ASA only under a doctor's orders,

SOME EXAMPLES OF INTERNAL ANALGESICS FOR SELF MEDICATION
(65 mg. = 1 grain)

Ingredients

Product name & Manufacturer	Dosage Form	ASA	Phenacetin	Salicy-lamide	Acetami-nophen	Others
Alka Seltzer (Mills Lab.)	tablet	342 mg.	–	–	–	
Anacin (Whitehall)	tablet	455 mg.	–	–	–	
Ascriptin (Rorer)	tablet	300 mg.	–	–	–	Magnesium hydroxide 75mg. Aluminum hydroxide 75mg
Aspergum (Bayer)	chewing gum	225 mg.	–	–	–	–
Aspirin (Bayer)	tablet	324 mg.	–	–	–	–
ASA USP BP (Various Manufacturers)	tablet	325 mg.	–	–	–	–
Bufferin (Bristol-Myers)	tablet	324 mg.	–	–	–	
Chemsal (Chemo Drug Co.Ltd.)	liquid suspension	–	–	325 mg per 5 ml.		–
Excedrin (Bristol-Myers)	tablet	325 mg.	–	130 mg.	–	
217 (Frosst)	tablet	375 mg.	–	–	–	Caffeine citrate 30mg
Salicylamide (Dymond Drugs)	tablet	–	–	325 mg.	–	–
Instantine (Sterling Drugs)	tablet	455 mg.	–	–	–	
Tempra (Mead Johnson)	tablet drops syrup	– – –	– – –	– – –	300 mg. 54 mg/0.6 ml 108 mg/5 ml.	–
Midol (Sterling Drugs)	tablet	486 mg.	–	–	–	
Tylenol (McNeil)	tablet drops elixir	 – –	 – –	 – –	325 mg. 60 mg/0.6 ml. 120 mg/5 ml.	–
Sinurex (Rexall Co.)	tablet	–	–	300 mg.		Phenylpropanolamine 25mg. Methapyrilene fumarate 10mg.

- internal bleeding which is more common in persons with stomach ulcers. Persons with ulcers should not take ASA and those with persistent stomach distress or indigestion should consult their physician before taking ASA,
- skin eruption or asthma-like symptoms in some ASA sensitive individuals.

2. Salicylamide

Effects

- similar action as ASA but somewhat less effective,
- reportedly causes less stomach disturbance than ASA. Persons who cannot tolerate ASA may be able to take products containing salicylamide,
- side effects of dizziness and drowsiness have been noted under certain conditions.

Permitted Dosages

- **Adults**

Single dosage — one to three—5 grain tablets or 325 mg to 975 mg.

Maximum daily dosage — nine—5 grain tablets or 2.925 grams.

Available also in liquid form, helpful for persons unable to take tablets and also in combination with other ingredients (see enclosed table).

3. Acetaminophen

Effects

- has analgesic and antipyretic properties but no anti- inflammatory effect,
- may be useful in patients who are sensitive to ASA,
- reportedly causes liver damage when taken in overdoses.

Permitted Dosages

- **Adults**

Single dosage — one — 5 grain tablet or 325 mg.

Maximum daily dosage — three—5 grain tablets or 975 mg.

Liquid forms are available (see enclosed table).

SELF MEDICATION

Drugs purchased without a prescription for self medication purposes do have a place in health care but it should be borne in mind that any drug can cause toxicity especially when used in excess. They should be used only when necessary. Abuse and misuse need to be controlled.

To control abuse of analgesics

- read label and take dosage recommended — you endanger your health by exceeding dose indicated, thinking it will be more effective.
- consult a doctor if pain persists and recurs over a period of time. The pain may be a symptom of something serious. Analgesics only relieve pain, they do not **cure** the cause.
- do not use headache tablets as sleep aids or for feelings of anxiety.
- if you reach for a pill every time you have a slight ache, beware — as this may mean you are developing a habit which may be hard to break.

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Health and Welfare Canada
Santé et Bien-être social Canada

NO 29
DATE December, 1973

NUTRITION CANADA NATIONAL SURVEY REPORT

A national nutrition survey, Nutrition Canada, was initiated by Health and Welfare Canada, in co-operation with the provincial governments, in the fall of 1970 to assess the nutritional status of Canadians.

The Nutrition Canada Survey, the most comprehensive nutrition study ever undertaken in Canada, was carried out over a period of two years (October 1970 to October 1972). During that time special clinics were held in 400 rural, urban and metropolitan communities to examine some 19,000 Canadians. The survey sample consisted of equal numbers of men and women from various age and income groups. Included in the survey, which covered all of the provinces and territories, were Eskimos, Indians and pregnant women as well as members of the general population.

Participants visiting the clinics underwent examinations which included a dietary interview, a physical exam, and a dental check. During the dietary interview, an in-depth record of the participant's food intake for the previous 24 hours as well as a more general report of his food consumption for the previous month were taken by a nutritionist. The physical exam involved a routine health check-up by a medical doctor followed by extensive anthropometric measurements to determine body size, height and weight. Blood and urine samples taken at this time were later analyzed at a central lab in Ottawa for evidence of nutritional deficiencies. The dental check was carried out to determine the condition of the participant's teeth, gums and mouth which helps to indicate one's nutritional status.

FINDINGS

The Nutrition Canada National Survey Report is the first of a series of reports to be published based on the data collected during the Nutrition Canada Survey. The National Report contains basic findings while later special reports will focus on individual provinces, groups (Eskimos, Indians) and subjects (dental health, food consumption patterns, etc.). The basic findings of the survey as outlined in the National Report are as follows:

Weight

The Nutrition Canada Survey shows that approximately half of the adults in Canada are overweight. Since the caloric intakes of those who are overweight and those who are not do not differ greatly, it would appear that our sedentary life style is probably a major cause of overweight Canadians, although too many calories over a long period of time certainly contribute to the problem.

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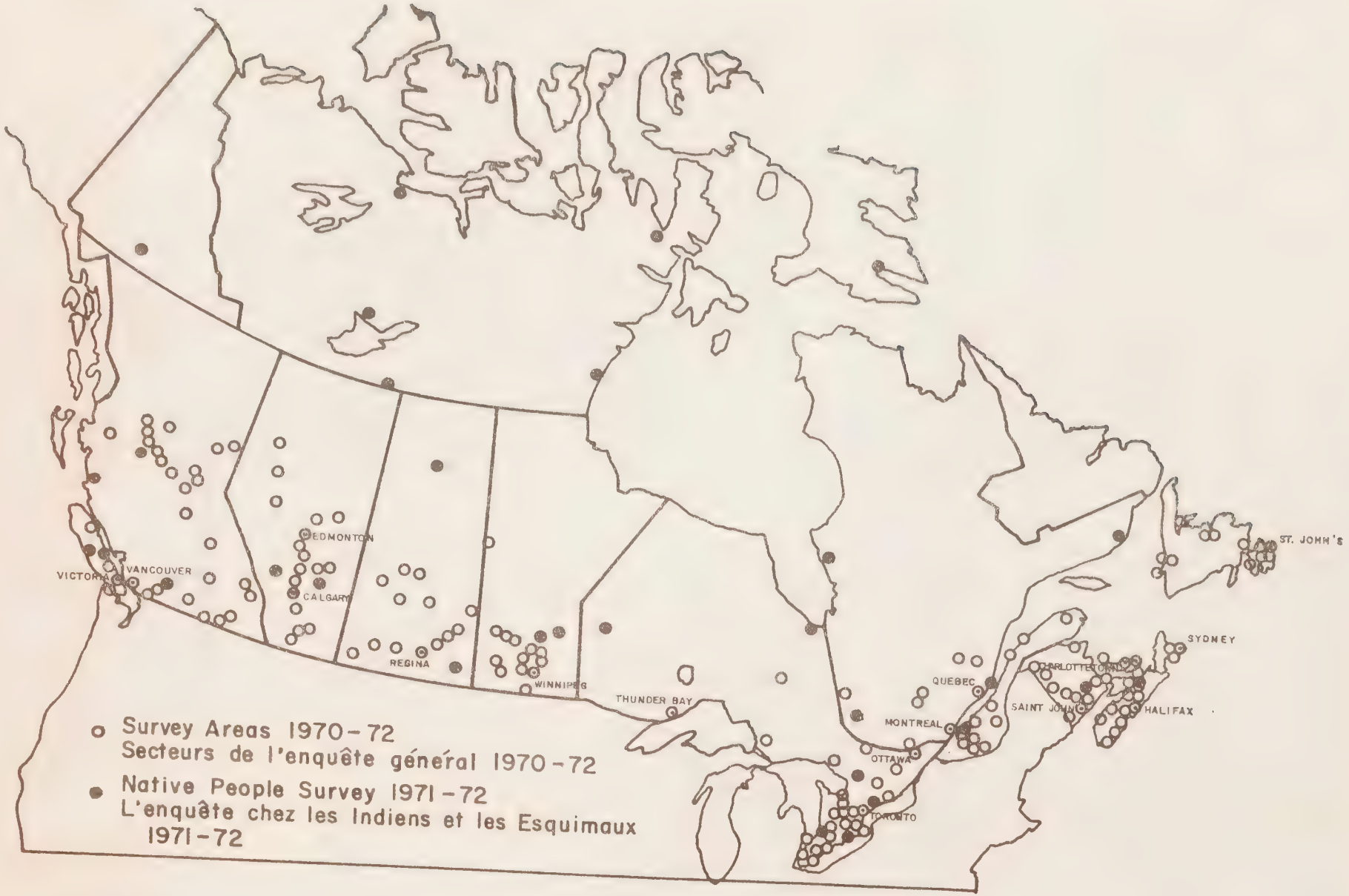
EDMONTON
VICTORIA
VANCOUVER
CALGARY
REGINA
WINNIPEG
THUNDER BAY
QUEBEC
MONTREAL
OTTAWA
TORONTO
SAINT JOHN
HALIFAX
SYDNEY
ST. JOHN'S
Survey Areas 1970-72
Secteurs de l'enquête général 1970-72
Native People Survey 1971-72
L'enquête chez les Indiens et les Esquimaux 1971-72

Iron

The biochemical and dietary assessment of iron indicates that large numbers of Canadians of all ages have an iron deficit. Many women have an iron deficit during pregnancy and many young children (0-4 yrs.) have low iron stores. Iron deficit is not only a problem of infants and women as had been previously assumed, but is a problem for some older children and men as well.

Protein and/or Calories

The results of Nutrition Canada also show a protein and/or caloric deficit among some pregnant women and a small proportion of children under 5 years of age. The importance to both the mother and child of adequate nutrition prior to and during pregnancy warrants major emphasis from all concerned with public health.

Calcium and Vitamin D

Shortage of calcium and vitamin D in the diets of many infants, children, adolescents, and pregnant women is another problem documented by Nutrition Canada. Adequacy of calcium and vitamin D during growth is essential for building a healthy skeleton and maintaining it throughout the adult years. Since fortified milk is a major dietary source of vitamin D, the shortage in dietary vitamin D indicates a low consumption of such milk by many Canadians.

Vitamin C

The survey gives some evidence of Vitamin C deficiency among Eskimos and, to a lesser extent, among Indians and the general population. The evidence includes clinical signs suggestive of vitamin C deficiency, low levels of serum vitamin C and a deficit of the vitamin in the diet.

Vitamin A

According to the report, there is a moderate vitamin A deficit among pregnant Indians and Eskimos. Low serum levels of vitamin A were also observed in many infants and toddlers, although their dietary intakes of the vitamin are satisfactory. There is no indication of vitamin A deficiency among adolescents and adults in the Indian, Eskimo and general populations.

Thiamin, Riboflavin and Niacin

The survey indicates that many adults, particularly men, in the general and Indian populations have a moderate thiamin deficiency. The status of riboflavin and niacin appears satisfactory.

Folic Acid

A surprising finding of the study is that large numbers of Canadians of all ages have low serum folate values. However, there is no clear clinical evidence of folate and B_{12} deficiency anemia. It is not possible to assess the clinical significance and public health consequences of these findings without further study. Folic acid, one of the B vitamins, plays a major role in the metabolism of the nucleic acids responsible for transfer of hereditary characteristics among cells and is utilized as well with iron in hemoglobin synthesis. Low levels in the serum are generally associated with low levels in tissues. This observation of Nutrition Canada should be viewed with concern, and appropriate steps taken to determine its significance to health.

Thyroid Size

The prevalence of moderate thyroid enlargement in the general population is another finding requiring further study as to its cause. Urinary iodine excretions indicate the amounts of iodine consumed are well in excess of body needs. It is unlikely that the goitre observed can be attributed to iodine deficiency. There is considerable variation in prevalence rates in different parts of the country; the highest rates occur in the prairie regions. It is evident that further research is required to define the cause and clinical significance of the apparent paradox.

Season, Income, Community Type

Preliminary analysis of the survey results revealed no consistent effect of season, income, or community type on the nutritional status of Canadians. The data collected for the Indian and Eskimo

populations have not yet been analyzed for these characteristics. Nutrition problems are essentially the same in summer as in winter and in metropolitan as in urban and rural areas. The fact that communities classified above the poverty line are generally plagued with the same nutrition problems as those in the poverty zone suggests that for most the critical factor is not money alone.

RECOMMENDATIONS

After identifying major national nutritional problems, the report suggests several priorities on which government and concerned groups should base their future action. These priorities involve:

- strengthening the government regulatory role in ensuring that the Canadian food supply is nutritionally adequate;
- developing effective programs by government and industry to inform and motivate the Canadian public to realize the value of nutrition;
- placing adequate emphasis in nutrition education programs regarding the concerns and vulnerability of certain segments of the population;
- emphasizing responsibility of the individual in adopting sound eating habits;
- gearing the training of health professionals to meet the nutritional needs of society;
- developing systems for monitoring and surveillance of the nutritional health of Canadians.

Hopefully, the combined efforts of governments, industry, and consumers in realizing these priorities will result in improved nutrition for all Canadians.

Copies of the Nutrition Canada National Survey Report are available to the public from Information Canada bookstores in Halifax, Montreal, Ottawa, Toronto, Winnipeg and Vancouver. They can also be ordered by writing to:

Information Canada,
171 Slater Street,
Ottawa, Ontario
K1A 0S9

When ordering the report by mail, enclose a cheque or money order for $2.75 made payable to the Receiver General of Canada.

Health and Welfare Canada
Santé et Bien-être social Canada

NO 30
DATE January, 1974

FOOD ADDITIVES

Modern technology enables us to gather fresh foods and food ingredients from all over the world, and food additives allow us to process those foods in a manner which ensures us an abundant food supply all through the year. The use of food additives has kept pace with technological advances in food processing and improved systems of food transportation. Meanwhile, as the use of additives has grown, so has concern about the necessity and safety of adding so many non-food substances to our foods.

WHAT IS A FOOD ADDITIVE?

Generally, a food additive is thought to be any substance added to a food as a result of production, processing, packaging or storing. The legal definition, however, is somewhat more restrictive. The Canadian Food and Drug Regulations define a food additive as "any substance, including any source of radiation, the use of which results, or may reasonably be expected to result in it or its by-products becoming a part of or affecting the characteristics of a food".

The definition does not include nutritive materials such as salt, sugar and starch as food additives, because each of them is "used, recognized or commonly sold as an article or ingredient of food". Other ingredients such as vitamins, mineral nutrients, amino acids, spices, seasonings and flavouring preparations are excluded from the definition as are pesticides, food packaging materials and veterinary drugs because each of these items is covered separately in the Food and Drug Regulations.

Food additives may be natural in origin, such as lecithin from soybeans, or synthetically produced, such as calcium propionate. Regardless of their origins, additives are chemicals, a fact that disturbs some consumers. That they are chemicals should not alarm us, however, since all foods, indeed all things, including man, may be viewed as composed of chemical entities. Actually, many common kitchen ingredients are chemical additives like vinegar (acetic acid), baking soda (sodium bicarbonate), and meat tenderizer (papain).

WHY DO WE USE FOOD ADDITIVES?

In 1955, the United Nations established the FAO/WHO Expert Committee on Food Additives to standardize the uses and purity of food additives. According to guidelines issued by the committee in 1956 and subsequently adopted by Canada, food additives are justified when they serve one or more of the following purposes:

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a) **"Maintaining the nutritional quality of a food;"**

For example, the vitamin A liquids which are added to certain milk products in Canada may break down unless protected. By adding an antioxidant such as butylated hydroxyanisole (BHA) to vitamin preparations destined for food use, the vitamin breakdown is prevented and the nutritional value of the vitamin is maintained so that is will be fully imparted to the food.

b) **"Enhancing the Keeping quality or stability with resulting reduction in food wastage;"**

Preservatives play a major role in extending the natural "life" of many foods (canned meats, baked goods, jams, jellies, etc.) so that they may be transported over vast distances, stored for considerable lengths of time and still be consumed safely.

c) **"Making foods attractive to the consumer in a manner which does not lead to deception;"**

Food additives such as colours and texture agents, are used in Canada to correct natural variations in foods so that a particular food looks, tastes, and performs the same way every time, thus making it attractive to the consumer.
A large variety of attractive convenience foods (snack-foods, one pan dinners, frozen desserts, etc.) are also made possible through the use of additives.

d) **"Providing essential aids in food processing;"**

Some food manufacturing processes require the use of stabilizing, clarifying, oxidizing and sequestering agents and other processing materials. The use of these substances often permits the economical large-scale manufacture of foods of constant composition and quality throughout the year.

WHAT ARE SOME COMMON TYPES OF FOOD ADDITIVES?

The use of food additives in Canada is purely optional, but when a manufacturer chooses to use food additives, he must choose from those listed in the 14 Food Additive Tables in the Food and Drug Regulations. The tables list the additive, the foods it is permitted in or upon, its purpose in those foods, and the maximum level of use. The additives are classified mainly by function, such as: preservatives, texture agents, pH-adjusting agents, colours, anti-caking agents, etc.

Preservatives maintain the appearance, palatability and wholesomeness of foods, because they retard or eliminate food spoilage caused by micro-organisms. Food spoilage is one of the world's most serious food problems. In fact, the World Health Organization (WHO) estimates that 20% of the world's food supply is lost through spoilage. Wider use of preservatives might possibly save most of that food. The two broad categories of preservatives are antimycotics and antioxidants.

Antimycotics prevent the formation of moulds and include additives such as sodium diacetate and calcium propionate (which prevent "rope" mould in bread), sorbic acid (which prevents mould in cheeses, syrup and confections), benzoic acid and sodium benzoate (which preserve fruit products, pickles and relishes) and sulphur dioxide (which inhibits mould and discolouration in wine, fruit pulps, fruit juice concentrates, and dried fruits and vegetables).

Antioxidants are added to fatty foods (cooking oils, dried breakfast cereals, potato chips, etc.) primarily to prevent rancidity; they are also used to keep fruit from darkening ("enzymatic browning") and foods packaged in transparent wrap from discolouring. Some common antioxidants are butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and ascorbic acid.

Another major group of additives is the **texture agents** which impart and maintain desired consistency in foods. Included in this group are emulsifiers, stabilizers, and thickeners. Emulsifiers permit the dispersion of tiny globules of one liquid in another (e.g. oil and vinegar dressing, mayonnaise); they also improve the volume, uniformity, and fineness of grain in bread and rolls. Stabilizers are used in products such as chocolate milk to keep the chocolate particles from separating and settling to the bottom, and in ice cream to prevent the formation of

ice crystals. Among the most common of these agents are gums such as carrageen and acacia gum, lecithin, mono and diglycerides. Thickeners such as agar, cellulose and pectin are used to regulate the consistency of jams and jellies and to thicken ice creams, frozen desserts, and confections.

pH adjusting agents which control the acidity or alkalinity (pH) of foods include acids, alkalies and buffering agents. These agents are used extensively for technological purposes in the manufacture of a variety of foods (baked goods, soft drinks, chocolate, etc.). Their effect may also be to slightly modify taste. Citric acid, for example, intensifies fruit flavours while sodium carbonate reduces the acidity of canned vegetables.

Colours, both natural and synthetic, constitute another class of additives. Some common examples are annatto, carotene, and caramel. They are added to food mainly to give it an appetizing appearance, because the way a food looks has a definite effect on its palatability. Colouring agents are permitted in soft drinks, frozen desserts, gelatin desserts, puddings and smoked fish, to name just a few.

Food additives used by the bakery industry include **bleaching** and **maturing agents**. Freshly milled wheat flour, which is yellowish in colour, will, if left alone, gradually whiten. Bleaching agents hasten this process and make it possible to have high quality flour quickly and consistently. **Leavening agents** such as yeast, baking powder, and baking soda, are also widely used in baked goods, because they react chemically to release carbon dioxide into the product being baked, giving it a lighter texture.

In addition to the additives previously mentioned, there are a number of other agents, such as:

- **Food enzymes** which act as catalysts to trigger desired chemical reactions in certain foods; for example, rennett is an enzyme used to curdle milk in the making of cheese;
- **Sequestrants** which are added to foods to inactivate ions of any metallic elements which may be present so they do not interfere with food processing. In fats and oils, for example, traces of unsequestered copper and iron could initiate processes leading to the development of rancidity;
- **Humectants** which maintain desired moisture levels in such foods as shredded cocoanut and marshmallows;
- **Anticaking agents** which are used in many salts and dried powdered mixes to keep them free-running;
- **Glazing agents** which make certain food surfaces shiny and in some cases protect the product from spoiling; they are used mainly in candies;
- **Firming and crisping agents** which maintain the texture of a number of processed fruits and vegetables (maraschino cherries, pickles, etc.) which would otherwise go soft;
- **Release agents** which help food separate from surfaces it touches during manufacture or transport: for example, they are used in removing bakery goods from baking pans without having them stick or crumble.
- Pressure-packed **foaming or whipping agents** which are used in dessert toppings to dispense the product in a whipped state;
- **Non nutritive sweeteners** like saccharin which are used to sweeten dietetic foods and contain no calories or food value.

WHO CONTROLS FOOD ADDITIVES?

The control of food additives in Canada is one of the responsibilities of the Health Protection Branch. The branch's food inspectors regularly examine food manufacturing plants to make sure the manufacturer is abiding by the additive specifications laid down in the previously mentioned Food Additive Tables. A manufacturer may be prosecuted if he uses additives in amounts violating the Regulations or additives which have not been officially added to the permitted list.

When a food additive is used in Canada, it must meet certain standards of purity such as those specified in the Canadian Food and Drug Regulations or the Food Chemicals Codex (FCC) published by the National Research Council of the United States. Canada has adopted FCC purity standards for some Canadian additives for which there are no specifications set out in the Food and Drug Regulations.

When a manufacturer wishes to introduce a new additive in Canada or use a permitted additive in a non-approved manner, he must submit an application to the Health Protection Branch containing the following information:

- physico-chemical properties of the product — chemical name, its composition and specifications.
- justification for use
- amounts to be used
- detailed reports of tests made to establish the safety of the food additive under the conditions of use recommended
- data to indicate residues that may remain in the finished food
- proposed maximum limit for residue of the food additive in or upon the finished food
- specimens of proposed labelling
- a sample of the food additive in the form in which it is proposed to be used and
- a sample of the active ingredient.

The submission is then evaluated by officers of the Health Protection Branch who report their findings to the Minister. The Minister then recommends acceptance or refusal of the new additive or additive use to the Governor-in-Council, who, in turn, approves or denies its addition to the additive tables.

ADDITIVE SAFETY

As was previously mentioned, when a manufacturer in Canada wishes to market a food product containing a new additive, he must include in his submission reports of animal studies which indicate that the additive will be safe for human consumption at proposed levels of use. These studies determine the dosage level of the additive which will have no discernible effect (ie., the "no effect level") in the most sensitive species of animals tested.

In an attempt to provide a quantitative expression of "safe" amounts of intentional food additives for the guidance of regulatory agencies, the concept ot Acceptable Daily Intake (ADI) was developed. The ADI is the daily dosage of a chemical which may be consumed for a lifetime without appreciable risk on the basis of all the facts known at the time. This is generally derived by dividing the "no effect level" obtained from animal studies by 100. The 100-fold safety factor is based on the premise that man may be more sensitive to the additive than other animals, and that certain men may be more sensitive than the norm.

Additives are also being continually reviewed by the Health Protection Branch. If new data indicates that a particular permitted additive may be hazardous, recommendation is made to have it removed from the Food Additive Tables. This has happened thirteen times in the last twenty years with additives such as Guinea green, diethylpyrocarbonate, and the cyclamates.

For several years, there has been considerable controversy over the use of food additives in Canada and internationally. However, no matter what one's views on additives may be, it is true that without them, many food products could not be offered for sale in their present form, and those that were available would be more expensive. The use of food additives allows for much of the variety and convenience in our food supply, and provided controls such as those outlined above are utilized, there should be no undue concern about the safety of using additives. Moreover, if food production is to keep pace with population growth and the effort to improve nutrition generally in undernourished areas, chemicals such as food additives will inevitably play an increasingly important role.

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Health and Welfare Canada
Santé et Bien-être social Canada

NO 30 (Revised)
DATE Summer 1977

FOOD ADDITIVES

Modern technology enables us to gather fresh foods and ingredients from all over the world; modern food processing ensures an abundant food supply throughout the year. The use of food additives has kept pace with technological advances in food processing and improved systems of transportation. But as the use of additives has grown, so has concern about the necessity and safety of adding so many non-food substances to our foods.

WHAT IS A FOOD ADDITIVE?

Generally, a food additive is thought to be any substance added to a food in the course of production, processing, packaging or storing. The legal definition, however, is more specific. The Canadian Food and Drug Regulations define a food additive as "any substance, including any source of radiation, the use of which results, or may reasonably be expected to result in it or its by-products becoming a part of or affecting the characteristics of a food".

Nutritive materials such as salt, sugar and starch are not considered to be food additives, because each of them is "used, recognized or commonly sold as an article or ingredient of food". Certain other ingredients are excluded from the definition because they are covered separately in the Food and Drug Regulations. These ingredients include vitamins, mineral nutrients, amino acids, spices, seasonings, flavouring preparations, agricultural chemicals, food packaging materials and veterinary drugs.

Food additives may be natural in origin, such as lecithin from soybeans; or synthetically produced, such as calcium propionate. Whatever their origin, additives are chemicals, and this fact disturbs some consumers. However, it is not a cause for alarm, since all foods, indeed all things including man, may be viewed as composed of chemicals. In fact, chemical additives include many common kitchen ingredients such as vinegar (acetic acid), baking soda (sodium bicarbonate) and meat tenderizer (papain).

WHY DO WE USE FOOD ADDITIVES?

Food additives are used in the manufacture of food for a variety of technological reasons. In Canada, their use is considered to be justified only if such use is in the interest of the consumer and when the additives serve one or more of the following purposes:

a) Maintaining the nutritional quality of a food;

For example, the Vitamin A preparations which are added to some milk products may break down unless protected. The addition of an antioxidant such as BHA (butylated

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SOME COMMON FOOD ADDITIVES

CLASS	FUNCTION	SOME EXAMPLES OF SPECIFIC ADDITIVES	FOODS IN WHICH THESE ADDITIVES ARE USED
ANTICAKING AGENTS	keep powders free-running	magnesium carbonate	icing sugar
BLEACHING AND MATURING AGENTS	hasten the natural process of whitening and maturing of wheat flour	chlorine	flour
CARRIER OR EXTRACTION SOLVENTS	used to dissolve flavours, colours and spices	ethyl alcohol	vanilla extract
COLOURS (natural and synthetic)	give food an appetizing appearance	carotene	butter, cheese
FOAMING OR WHIPPING AGENTS	enable pressure-packed products to be dispensed in a whipped state	nitrogen	dessert toppings
FIRMING AND CRISPING AGENTS	maintain the texture of fruits and vegetables	calcium chloride	canned vegetables
FOOD ENZYMES	act as catalysts to initiate desired chemical reactions	rennet	curdling milk in the making of cheese
HUMECTANTS	maintain desired moisture levels	sorbitol	shredded coconut, marshmallows
pH-ADJUSTING AGENTS (acids, alkalis and buffering agents)	control the acidity or alkalinity (pH) of foods; modify flavour slightly	sodium bicarbonate	baking powder
PRESERVATIVES -antimicrobial agents	inhibit the growth of moulds, yeasts or bacteria	sodium diacetate	bread
-antioxidants	prevent rancidity and oxidative discoloration	butylated hydroxytoluene (BHT)	cooking oils
RELEASE AGENTS	help food separate from surfaces it touches during manufacturing or transport	mineral oil	baked goods (to remove from baking pans without sticking or crumbling)
TEXTURE MODIFYING AGENTS (emulsifiers, gelling agents, stabilizers and thickeners)	impart and maintain a desired consistency in foods	mono and diglycerides	ice cream

hydroxyanisole) prevents destruction of the Vitamin A.

b) Enhancing the keeping quality or stability with resulting reduction in food wastage;

Preservatives play a major role in extending the natural "life" of many foods (canned meats, baked goods, jams, jellies, etc.,) so that they may be transported over vast distances, stored for considerable lengths of time and still be consumed safely. The World Health Organization (WHO) estimates that 20% of the world's food supply is lost through spoilage. Without preservatives, this percentage would be much higher.

c) Making foods attractive to the consumer in a manner which does not lead to deception;

Food additives such as colours and texture agents are used in Canada to correct natural variations in foods so that a particular food looks, tastes, and performs the same way every time. The use of additives also makes possible a large variety of attractive convenience foods (snack foods, one-pan-dinners, frozen desserts, etc.).

d) Providing essential aids in food processing;

Some food manufacturing processes require the use of processing materials such as stabilizing, clarifying and oxidizing agents. The use of these substances permits the economical large-scale manufacture of foods of constant composition and quality throughout the year.

When a manufacturer chooses to use a food additive, he must choose from those listed in the Food Additive Tables in the Food and Drug Regulations which classify additives according to function. The Tables list the additive, the foods in or upon which it is permitted, its purpose in those foods, and the maximum level of use.

WHAT ARE SOME COMMON TYPES OF FOOD ADDITIVES?

The table on page 2 describes the functions of some common classes of food additives, and gives specific examples.

WHO CONTROLS FOOD ADDITIVES?

The control of food additives in Canada is a responsibility of the Health Protection Branch. The Branch's food inspectors regularly examine food manufacturing plants to ensure that the manufacturer is abiding by the provisions laid down in the Food Additive Tables. A manufacturer may be prosecuted if he uses additives in amounts violating the Regulations, or additives which have not been added to the permitted list.

When a manufacturer wishes to introduce a new additive, he must submit an application to the Health Protection Branch. Among other information, this submission must include reports of controlled studies which indicate that the additive will be safe for human consumption at proposed levels of use. These studies normally include animal studies to determine the dosage level of the additive which will have no discernible effect (i.e., the "no effect level") in the most sensitive species of animals tested.

ADDITIVE SAFETY

The concept of Acceptable Daily Intake (ADI) is used to provide a quantitative expression of safe amounts of intentional food additives for the guidance of regulatory agencies. The ADI is the daily dosage of a chemical which may be consumed by humans for a lifetime without discernible risk, on the basis of all the facts known at the time. This is generally derived by dividing the "no effect level", obtained from animal studies, by 100. The 100-fold safety factor is based on the premise that man may be more sensitive to the additive than other animals, and that certain individuals may be more sensitive than the norm.

Additives are also being continually reviewed by the Health Protection Branch. If new data provide evidence that the use of a particular additive poses a hazard to the consumer, recommendation is made to have it removed from the Food Additive Tables. Guinea green, diethyl pyrocarbonate, and saccharin are examples of food additives which have been deleted in recent years.

Meanwhile, there has been considerable criticism of the use of food additives, both in Canada and internationally. But without additives, many food products could not be offered for sale in their present forms, and the remaining products would be much more expensive. The use of additives has made possible much of the variety and convenience found in our food supply. Moreover, if food production is to keep pace with population growth and the effort to improve general nutrition in undernourished areas, the use of food additives will become increasingly important.

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Health and Welfare Canada
Santé et Bien-être social Canada

Government Publications

NO 31
DATE February, 1974

THE TELEVISION SET AND X-RADIATION

What is x-radiation?

X-radiation is just one form of *radiation*, the transmission of energy through space. Radiation may be *electromagnetic*, like x-rays and light, or *vibrational*, like sound. It may originate from *background* or *man-made* sources. *Background radiation* is present in our environment as electromagnetic radiation from natural radioactive materials in our bodies and around us and cosmic radiation from space.

We have no control over background radiation, but we are responsible for the beneficial and harmful effects of *man-made radiation*, both vibrational and electromagnetic.

Electromagnetic radiation may be categorized as either ionizing or non-ionizing.

Ionizing radiation, such as from radioactive material or x-ray machines, has the ability to strip electrons from atoms, creating ions which are electrically charged. Such radiation is capable of affecting life processes.

Non-ionizing radiation, such as visible light, ultraviolet, infrared and microwaves lacks the ability to create ions but can still adversely affect human health.

Effects of radiation in humans can be somatic or genetic.

Somatic effects are injuries which manifest themselves in the exposed individual during his lifetime and may show up as skin rashes, cataracts, or cancers.

Genetic effects are changes or mutations in the genetic material of reproductive cells and may show up as defects in future generations.

Radiation devices

Our utilization of man-made radiation can be found in the health professions, industry, and the home.

- **Health Professions** — We are all familiar with the use of x-ray machines in medicine and dentistry for diagnostic purposes.
- **Industry** — In industry, radiation gauges are used on many production lines to control levels of fluids or thicknesses of paper, aluminum, copper, steel, glass, and other materials. Radiation is also used to detect flaws in the construction of many industrial materials such as pipes and castings.
- **Home** — In the home, radiation is incorporated in appliances such as microwave ovens and radium-dial clocks.

All of the radiation emitting devices cited above use radiation as a tool, an integral part of certain operating processes. Sometimes, however, the production of radiation is unintentional. Such is

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the case with television receivers, which emit x-radiation as an unnecessary by-product. How is the radiation emitted by television sets produced? Are there standards to control such radiation? If so, what are they, and how are they being enforced?

Where do the x-rays come from?

In television sets, three components have the capability of producing x-radiation: the picture tube, the high voltage regulator, and the high voltage rectifier tube. The intensity of x-radiation from each source depends on the tube voltage and current.

- **Picture Tube** — Maximum emissions from the picture tube will occur when there is a bright picture on the screen or when the picture does not completely fill the screen.
- **Regulator Tube** — The regulator tube will emit maximum radiation when the picture tube is dark.
- **Rectifier Tube** — Radiation emissions from the rectifier tube will occur when the reverse current portion of the cycle goes into effect.

X-radiation can be reduced in intensity when any material is placed in the x-ray beam. In television sets, glass, metal and ceramic components interrupt x-ray beams because of their positions in the set relative to the x-ray emitting sources mentioned above. In most TVs, this accidental interruption of x-ray beams is enough to reduce x-radiation to minute levels. Most manufacturers provide additional shielding of the radiation-emitting elements in the television as an added safety precaution. When properly designed and manufactured under rigid quality controls, televisions present no x-radiation hazard if:

1) they are operated at the manufacturer's specified power line voltage and
2) they have all the factory installed shields and equipment in place.

Black and white VS. colored sets

Because the amount of radiation they emit is almost nil, black-and-white televisions have never been a source of concern. Color televisions, however, have come under suspicion as potential radiation hazards in past years because of the increased penetrating power of x-rays produced as a result of higher voltage.

Following a report from the United States in the late 1960s that certain 1966 models of a particular brand name color TV had been found to emit excessive amounts of ionizing radiation, Canada's Radiation Protection Bureau undertook a survey of its own to determine the extent of potentially dangerous levels of radiation being emitted by color television receivers in Canada. The Canadian survey, conducted on TVs purchased in 1969 or earlier, showed that about 11% of the sets tested emitted radiation above the accepted standard of 0.5 milliroentgen/hour (international unit of x-radiation measurement). However, the standard carries such a high safety margin that, unless a TV's radiation emission exceeded that standard by a substantial amount, the health risk in watching such a set would be very small.

Standards for television receivers

Standards for television receivers resulting from the 1969 survey have been in force as Regulations under the Radiation Emitting Devices Act (REDAct) since June of 1972. These Regulations limit x-ray emission to a maximum of 0.5 milliroentgen/hour (same as the International Standard) at the outside surface of the set. All new television sets now sold in Canada are designed to operate in compliance with the Regulations. Health Protection Branch inspectors regularly inspect the premises of plants which manufacture radiation emitting devices, including televisions, to make sure that the manufacturers do comply with the Regulations.

The REDAct Regulations do not apply to television receivers already in use which were manufactured prior to the issuing of the Regulations in 1972. Safe use of such receivers, even in cases where radiation emission is somewhat in excess of the accepted standards, can be achieved by adhering to the following safety rules issued by the Radiation Protection Bureau.

Safety rules for viewers

1. Do not attempt your own servicing; consult an authorized repairman.

2. On his next service call, ask the repairman to check the voltage regulating circuits and radiation shielding as specified by the manufacturer.

3. If your set was manufactured prior to 1972, avoid sitting closer than 4-6 feet from the set, and do not allow children to lie with legs extended beneath the set while viewing.

4. Place all color television sets against a wall; do not locate chairs immediately adjacent to the side or back. Leakage radiation, if present, is most likely from the rear or sides, not from the front of the set.

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Dispatch No. 32

Microbial Food Poisoning

Food-borne disease is of major significance to the Canadian public. The average number of cases recorded by the national Food-borne Disease Reporting Centre annually is approximately 5000. Epidemiological studies, however, have shown that probably only one case in 25 is reported to health authorities. The tell-tale symptoms of nausea, vomiting, diarrhea and stomach cramps are often misdiagnosed by sufferers and physicians alike as virus infections. It is suspected, therefore, that the annual number of cases is at least 125 000 and quite possibly as high as 500 000.

Microbial Infections and Intoxications

The most common causative agents, by far, are microbiological, in particular *Salmonella* species, *Staphylococcus aureus* and *Clostridium perfringens*. They can multiply rapidly in moist, warm, protein-rich foods such as meat, poultry, fish and shellfish, milk, eggs and in most canned food. These microbes may act in one of two ways - as infectious organisms or as toxigenic organisms.

Infectious organisms, (e.g. *Salmonella*) once they are eaten, can multiply in a person's digestive tract and cause illness either by invading the tissue or by producing toxins to cause gastroenteritis. Most infectious food-poisoning organisms are heat sensitive and their numbers in food can be controlled through adequate cooking and subsequent refrigeration.

Toxigenic organisms (e.g. Staphylococci) themselves are quite harmless when eaten; their danger lies in the poisonous toxins which they produce in food. Some toxins are especially dangerous because they are heat stable; that is, once they are formed, even extended cooking at high temperatures will not destroy them.

Factors in the Growth of Food-poisoning Organisms

Prime factors affecting the growth of such organisms in our foods are time-temperature, moisture and acidity.

Time-Temperature

While little can be done about some factors, the rate of growth can be reduced if foods are kept either hot or cold. Susceptible foods, such as meat, milk or egg-containing products, left for more than two hours at temperatures between 4°C and 60°C (40°C and 140°F) are in the **Danger Zone**. They may be hazardous and should be discarded. Micro-organisms can multiply rapidly at room temperature. In fact, many food-poisoning bacteria can double in number every 15 minutes at optimum temperatures for growth 35°C - 45°C (95°F - 113°F).

Below 4°C (40°F), the growth of most organisms is inhibited. Above 60°C (140°F), heat will kill most organisms and inhibit the growth of others.

Moisture

Food-poisoning organisms favour foods abundant in moisture. Certain liquids and semi-solid foods, such as syrups and jams, can be safely stored at room temperature only because they have high concentrations of sugar which ties up the moisture, thereby making it unavailable to bacteria. Salt is also used in some foods for the same reason.

Acidity

The acidity of foods (called the pH) is another factor. Acidic conditions usually inhibit the growth of food poisoning and most spoilage organisms. This is why it is possible to preserve some foods by pickling without boiling them. The amount of vinegar used in the pickling process generally lowers the pH sufficiently to inhibit the organisms from proliferating.

Packaging

Today, many food items offered for sale are packaged under vacuum or under a so-called modified atmosphere. The impression is frequently given that foods so packaged keep better and longer, and refrigeration is not all that critical.

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It may be true that freshness and flavour are retained longer because of the absence of air, and such products will not spoil easily. This may be considered an additional advantage. However, since many of these foods are uncooked or only partially cooked, they are by no means shelf-stable as are canned foods.

The absence of air will retard the growth of most common spoilage bacteria. However, there are some pathogens such as source strains of *Clostridium botulinum* and *Listeria monocytogenes* that are able to grow in the absence of air even at low temperatures. This makes prompt and proper refrigeration of these products all the more important since the food may become a health hazard without becoming spoiled.

Governmental Protection against Food Poisoning

One of the prime objectives of the Health Protection Branch of Health and Welfare Canada is to ensure a safe food supply for Canadians. This is done through legislation, inspection and analysis, research and education.

Legislation

Through the provisions of the Food and Drugs Act and Regulations, the Health Protection Branch has control over the manufacture of food products sold in Canada. General protection against food poisoning is provided for in the Act. Section 7, for example, states that "No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions."

Section 4 is even stronger in that it prohibits the sale of any food that is unfit for human consumption; consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed, or diseased animal or vegetable substance; is adulterated; or was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Additionally

*In 1981, the Health Protection Branch officially adopted the international "Code of Practice General Principles of Food Hygiene" as a voluntary good manufacturing practices guideline to assist the food industry in meeting and the Health Protection Branch in enforcing, the intent of the Food and Drugs Act.

This code was produced by the Codex Alimentarius Commission which is a joint office of the Food and Agriculture Organization of the United Nations and the World Health Organization.

In addition to the general protection afforded by parts of the Act itself, there are specific regulations dealing with particular foods prone to contamination with food-poisoning agents. Some examples are:

Ready-to-Eat Store-Cooked Meats - Meats or meat by-products which have been barbecued, roasted or broiled and are offered as "ready-to-eat" products may not be sold unless they have been stored at temperatures below 4°C (40°F) or above 60°C (140°F) at all times and carry a statement on the label advising the purchaser to store them at such temperatures until consumption.

Cheese - Under the dairy products regulations, no cheese, whether made from a pasteurized or unpasteurized source, may exceed specified limits for *E. coli* or *S. aureus*.

Eggs - In order to be offered for sale, liquid, dried or frozen egg products must be free of *Salmonella* bacteria.

Inspection and Analysis

Field Operations inspectors carry out regular inspections of food-manufacturing plants and storage warehouses to ensure compliance with the Regulations. This provides an opportunity to detect operating deficiencies and initiate corrective action before defective products reach the marketplace. Inspectors look at various factors which may cause or contribute to health hazards in:

- the immediate plant environment and surrounding neighbourhood;
- the construction, design, lay-out or maintenance of plant buildings and facilities;
- all aspects of production (e.g. raw material receipt and handling, processing, packaging or storage);
- the training and employment of personnel involved in production (unsatisfactory work habits, health problems);
- equipment age, design, suitability or state of repair;
- the sanitary conditions of plant, equipment and personnel;
- quality control procedures in production; and
- the attitude of management regarding sanitary procedures and quality control.

In addition, inspectors are often involved in investigating food-borne disease outbreaks.

During inspections, food samples, both raw and processed, are collected for analysis at the regional laboratories. Samples (about 12 000 annually) are analysed for microbiological and chemical safety and nutritional quality. Food safety assessment projects (e.g. evaluating frozen, pre-cooked entrées for microbiological quality) are also carried out at these laboratories to help develop definitive and dependable information to ensure early detection and elimination of infectious organisms or unsanitary practices in preparation and handling.

Research and Risk Assessment

The Bureau of Microbial Hazards is responsible for food-safety-related research, the setting of microbiological standards in foods and evaluating information and data pertaining to food safety.

The Research Division develops sensitive and specific methods for the detection of food-borne pathogens and their toxins, and carries out other related investigations.

In instances of food-borne illness outbreaks, or when contaminated food is found in commerce, the Bureau through its Evaluation Division, provides risk assessment and advice, and makes recommendations for protecting the Canadian consumer and for improving the performance of the producer.

The Health Protection Branch, through its Food-borne Disease Reporting Centre, collects data listing the number of incidents and cases, casual agents, implicated foods, places of acquisition and mishandling, month of onset and regional distribution of food-borne diseases in Canada. These data, published in annual summaries, are useful in determining why problems occur and where control measures or educational programs might be helpful in preventing recurrences.

Education

In addition to its legislative, research and inspection activities, the Health Protection Branch is involved in programs and publications designed to educate consumers and health professionals about the dangers and prevention of food poisoning. Field Operations inspectors also provide information to the food industry on proper operating procedures. Since a defective product has the potential of reaching many people before the hazard is detected, both food manufacturers and food service operators need to be well versed in maintaining sanitary conditions and quality standards.

According to the Food-borne Disease Reporting Centre, the latest data indicate that 56 percent of food-poisoning cases were caused by mishandling in food-service establishments (cafeterias, restaurants, mobile canteens, etc.). Another six percent of cases resulted from mishandling in the home and six percent were associated with problems at food-processing companies. For most of the remaining 32 percent, the places of mishandling could not be determined.

Preventive Measures for Consumers

The federal departments of Agriculture, Consumer and Corporate Affairs and Fisheries and Oceans, as well as provincial and municipal health departments, all have programs on food-poisoning prevention and cooperate with Health and Welfare Canada in those areas where the departments' interests coincide.

However, the government as well as the food industry can only go so far in protecting Canadians against the hazards of food poisoning. In the home, food safety is the consumer's responsibility. It is up to the consumer to handle foods carefully until they are prepared and served. Two keys to preventing food poisoning are temperature control and sanitation. The following prevention measures should be observed.

Temperature Control

As previously mentioned, keeping susceptible foods out of the **Danger Zone** (4°C - 60°C or 40°F - 140°F) will help prevent most bacterial growth. Some of the potentially unsafe foods which deserve special attention are meat, poultry and fish dishes, gravies, stuffings, custards and puddings, eggs and cream-filled desserts. These foods should be thoroughly cooked and kept hot (above 60°C or 140°F internally) or refrigerated (below 4°C or 40°F internally) until serving. Do not keep food warm in the oven. If a susceptible product has not been refrigerated within two hours of purchasing or has been removed from the refrigerator for more than two hours, it would be wise to discard it. Remember too, that food in bulk quantities will take a long time to cool down even in the refrigerator and also to become hot when reheated. Keep a thermometer in the refrigerator and freezer to ensure proper temperature control. (See chart below.)

Critical Temperatures for Safe Food Handling

Internal Temperature - Centre

Operation	°C	°F
Pressure Canning	116° - 127°	240° - 260°
Cooking	74° plus	165° plus
Warm Holding	60° plus	140° plus
Refrigeration	2° - 4°	35° - 40
Frozen Storage	-18° or less	0° or less
Dishwasher Rinse	65° plus	150° plus

Sanitation

Sanitary food-handling practices will also help prevent food poisoning. When preparing food, keep hands, utensils (including can openers) and work area clean to limit the cross-contamination of one food from another. Thoroughly clean with hot, soapy water all surfaces that have contacted raw poultry since this type of food often has *Salmonella* bacteria in the carcass. Keep the work area free of flies and other insects which might spread bacteria. If possible, don't

handle food when ill; keep all cuts on hands clean and covered, make sure the mouth is covered during a cough or sneeze and rewash hands afterwards.

Also store foods properly. Make sure raw food does not contaminate cooked food. Because some food-borne pathogens can grow albeit slowly at refrigeration temperature, avoid leaving food in the refrigerator for a long period of time. Label foods properly so there is no confusion with ingredients. Do not keep pesticides or other toxic chemicals in the kitchen where food may become contaminated.

Freezer Breakdown

Food will usually stay frozen for two days if a non-functioning freezer is filled to capacity. If the freezer is less than half full, food will only keep frozen about 24 hours. Open freezer as little as possible to check on food's coldness. Food can also be kept frozen for three or four days by using dry ice, placed on cardboard laid on top of the food.

Generally, food that has some ice crystals and no obvious signs of deterioration can be refrozen. It is best to immediately cook foods that are completely thawed, but still cold. It is also prudent to discard susceptible foods that are thawed and have been held at room temperature for an unknown period of time.

Safety Precautions

A slimy coating around food or putrid smell are sensory clues to the presence of microbial contamination. However, others may not be so obvious. The presence of botulinal toxin, for example, which is one of the deadliest forms of a food-associated poison, may not be evident at all. Therefore, it is up to the consumer to adhere to the temperature, time and other safety guidelines.

In the area of canned foods, although manufacturers take special precautions when processing, consumers should avoid using any cans that are badly dented, bulging or leaking as well as those, which when opened, appear bubbly or spurt out their contents.

Do not eat food that is rotten, putrid or sour tasting - it probably means there is microbial contamination and ingestion will result in illness. At greatest risk are seniors, the very young and ill persons.

Processed products suspected of contamination should be reported to the store manager *and* the local municipal health unit or the nearest Health Protection Branch office. It is important that the imprinted code number on the suspected product be kept so that the problem can be traced to its source and fully investigated.

Consumers who do canning or preserving in the home would be wise to follow the safety procedures.

By reporting suspected cases of food poisoning to the local municipal health unit or the Health Protection Branch, consumers may not only prevent others from similar suffering, but also indirectly assist the Branch in developing a more accurate data base for research.

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* Materials Available from Nearest HPB Office

Publications

Aflatoxin Analyses for Consumer Protection - Dispatch No. 26

Canned Foods: Keeping the Lid on Contamination - Tearsheet

Code of Practice General Principles of Food Hygiene. For use by the Food Industry in Canada

Danger Zone in the Kitchen - Worksheet

Food Safety - It's All in Your Hands - Booklet

Handling poultry...safely - Tearsheet

Mould - More than Meets the Eye - Tearsheet

Recipe for Safe Food Handling - Poster

Audio-visuals

Uninvited Guests to Dinner is available in film strip/sound and has been produced for the general public, health professionals, educators and food handlers. The film presents dramatizations of four actual events where poor handling and preparation practices resulted in serious incidents of food poisoning. Information on how to avoid food poisoning at home, in a food service establishment or in an institution, is presented. The film features drama, attractive graphics and music.

Selected Causes of Microbial Food Poisoning

Disease and Food-poisoning Agent	Frequency and Seriousness	Symptoms	Onset and Duration of Symptoms	Habitat and Foods Commonly Involved
Staphylococcal food-poisoning *(Staphylococcus aureus)* toxin resistant to boiling	Frequent; death is rare	Cramps, nausea, vomiting, diarrhea	Onset 1-6 hrs. after eating; lasts 1 day	Found in nose and throat of most people; foods - ham, cooked poultry, meat or potato salads, fish
Botulism *(Clostridium botulinum)* anaerobic bacteria; toxin destroyed by boiling	Rare; death may occur	Double vision, dry mouth, nervous system affected, paralysis	Onset 1 day to 1 week after eating; recovery slow	Found in most soils; foods - underprocessed, home-canned or commercial vegetables, fish and meats
Perfringens food-poisoning *(Clostridium perfringens)*	Frequent; death is rare	Diarrhea, cramps	Onset 8-24 hrs. after eating; lasts 1 day	Found everywhere, especially in gut of animals; foods - meats, stews, gravies, especially in bulk quantities
Salmonellosis *(Salmonella)*	Frequent; occasional death for aged, infants, infirm	Cramps, chills, vomiting, diarrhea, fever	Onset 8-24 hrs. after eating; usually lasts 2-3 days, but may last for weeks	Found in gut of domestic animals, especially chickens; foods - poultry, meat and egg products
Bacillus cereus poisoning *(Bacillus cereus)*	Fairly frequent; death unknown; two types	Type 1 Nausea, cramps, diarrhea	Onset 8-16 hrs. after eating; lasts 1 day	Found everywhere, e.g. dust, soil; foods - cereal products, custards, meat loaf, chicken à la king
Campy *L.M.* *Enteropathic E. Coli*		Type 2 Nausea, vomiting	Onset 1-6 hrs. after eating; lasts 1 day	Found everywhere, e.g. dust, soil; foods - rice, particularly Chinese-type food

Prevention Measures: All these illnesses can be prevented by reducing the contamination of food as much as possible (using approved ingredients and sanitized equipment) and by not allowing the organisms to grow (keeping food hot or cold with as little preparation at room temperature as possible).

Uninvited Guests to Dinner is available in:

Filmstrip/Sound - 20 minutes

This filmstrip with teacher's resource guide ($59.00) may be purchased from:

McIntyre Educational Media Ltd.
30 Kelfield Street
Rexdale, Ontario
M9W 5A2

Published by authority of the Minister of National Health and Welfare

Egalement disponible en français sous le titre
"Les intoxications alimentaires d'origine microbienne"

Cat. No. H49-46/4-1990E
ISBN 0-662-17422-4

Health and Welfare Canada
Santé et Bien-être social Canada

NO 32
DATE March 1974

MICROBIAL FOOD POISONING

Food-borne illness, more commonly known as food poisoning, affects thousands of Canadians each year. Its symptoms may range from mild nausea and discomfort to violent fits of vomiting, cramps and diarrhea. Occasionally, it results in death. Food-borne illness may be caused by either chemical or microbial agents.

Microbial food poisoning is far more prevalent and complicated than chemical food poisoning. While most of the bacteria in our environment are beneficial or harmless, there are a few strains which can cause food poisoning and other illnesses. For the purposes of discussion, the bacteria which cause food-borne illness may be divided into two categories, toxinogenic and infectious microorganisms.

- **Toxinogenic** organisms themselves are quite harmless when eaten in moderate amounts; their danger lies in the potentially poisonous toxins which they produce in food. Some toxins are especially dangerous because they are heat stable; that is, once they are formed, even extended cooking at high temperatures will not kill them. Other toxins are heat labile and will be destroyed by adequate cooking.
- **Infectious** food poisoning organisms do not usually produce toxins when growing in food; the organisms themselves cause illness when eaten in large numbers, or, occasionally, even in small numbers. In most cases, multiplication of the organism in the gut is required to cause illness. Most infectious food poisoning organisms are quite heat labile and can be controlled through adequate cooking and refrigeration.

TEMPERATURE CONTROL

Both types of microbial food poisoning agents multiply most rapidly in temperatures between 40° and 122° F (4° — 39° C). Temperatures between 40° — 140° F (4° — 60° C) are considered to be **THE DANGER ZONE**. Therefore, it is extremely important to keep foods out of this range to prevent bacterial growth. Observe the following temperature guidelines when handling food:

*CRITICAL TEMPERATURES FOR SAFE FOOD HANDLING**

Operation	Internal Temperature ° F	° C
Home Canning	240° — 260°	116° — 137°
Cooking	165° plus	74° plus
Warm Holding	140° plus	60° plus
DANGER ZONE	40°— 140°	4°— 60°
Refrigeration	35°— 40°	2°— 4°
Frozen Storage	0° or less	-18° or less

*Adapted from *FDA Papers*, June 1972.

Educational Services, Health Protection Branch

SELECTED CAUSES OF MICROBIAL FOOD POISONING

Disease & Food Poisoning Agent	Frequency & Toxicity	Symptoms	Onset & Duration of Symptoms	Habitat & Foods Commonly Involved	Preventative Measures
TOXINOGENIC					
Staphylococcal food poisoning *(Staphylococcus aureus* heat stable toxin	Most common; death is rare	Cramps, nausea, vomiting, diarrhea	Onset 1–6 hrs. after eating; last 1 day	Found in nose & throat of most people; foods — baked ham, roast fowl, meat or potato salads, fish, cream desserts	Temperature control; sanitary food handling practices
Botulism *(Clostridium botulinum)* anaerobic bacteria; heat labile toxin	Rarest; death frequent; mortality rate at least 50%	Double vision, infection of nervous system, then paralysis	Onset 1 day to 1 week after eating, paralysis and/or death; recovery slow.	Found in most soils; foods — underprocessed home-canned or commercial vegetables, fish & meats	Temperature control through adequate cooking & refrigeration
INFECTIOUS					
Perfringens food Poisoning *(Clostridium perfringens)*	Very common; death is rare	Diarrhea, cramps	Onset 8–24 hrs. after eating; last 8 hrs.	Found everywhere, espec. in gut of animals; foods — meats, gravies	Temperature control through adequate cooking & immediate refrigeration or holding at above 140 °F.
Salmonellosis *(Salmonella)*	Very common; occasional death for aged, infants, infirm	Cramps, chills, vomiting, diarrhea, fever	Onset 8–24 hrs. after eating; usually lasts 2–3 days, but may last for weeks	Found in gut of domestic animals, espec. chickens; foods — poultry, eggs & egg products	Temperature control; sanitary food handling practices
Shigella poisoning *(Shigella)*	Uncommon; death unknown	Cramps, diarrhea	Onset 7–66 hrs. after eating, lasts 1/2 day to 1 week	Found in sewage contaminated water; foods — milk, ice cream	Sanitation
E. coli poisoning *(Escherichia coli)*	Uncommon; death unknown	Cramps, diarrhea, vomiting	Onset 6–36 hrs. after eating; lasts 1/2 day to 1 week	Found in sewage contaminated water; foods — shellfish	Sanitation

GOVERNMENTAL PROTECTION AGAINST FOOD POISONING

One of the prime objectives of the Health Protection Branch of Health and Welfare Canada is to ensure a safe food supply for Canadians. This is done through legislation, inspection, research, and education.

Legislation

Through the provisions of the *Food and Drugs Act and Regulations*, the Health Protection Branch has control over the manufacture and distribution of all food products sold in Canada. General protection against food poisoning is provided for in clauses of the Act such as the one which states that "no person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions".

In addition to the general protection afforded by parts of the Act itself, there are several specific regulations dealing with particular foods prone to become contaminated with food poisoning agents. Some examples are:

- **Vacuum-packed meats** — The regulations dealing with vacuum-packed meats stipulate that, at the time of packaging, such meats must be free of microorganisms capable of producing toxins; and after packaging, such meats must be stored continuously under refrigeration.
- **Ready-to-eat store-cooked meats** — Meats or meat by-products, such as barbecued chicken, which are barbecued, roasted, or broiled on the vendor's premises and offered as "ready-to-eat" products may not be sold unless they have been stored at temperatures below 40° F (4° C) or above 140° F (60° C) at all times and carry a statement on the label advising the purchaser to store them at such temperatures until consumption.
- **Cheese** — Under the dairy regulations, no cheese made from unpasteurized milk may be sold until stored for at least 60 days, in which time many harmful bacteria will have died out. Other regulations deal with specific food poisoning organisms.
- **Eggs** — In order to be offered for sale, egg products must be free of *Salmonella*.
- **Fish** — Smoked fish, if vacuum-packed, must be heated to destroy *Clostridium botulinum*, or sold as a frozen product.

Inspection

Periodic inspections of food manufacturing plants and retail outlets ensure that members of the food industry maintain quality control and comply with these and other regulations concerning the foods susceptible to food poisoning contamination.

Research

In its modern food research labs, the Health Protection Branch carries out Food Safety Assessment projects to study foods commonly implicated in food poisoning, to develop new ways of making them safer, and to improve methods of detecting food poisoning agents in such foods.

Education

In addition to its legislative, research and inspection activities, HPB is involved, through the efforts of Educational Services, in programs designed to educate the public and members of the food service industry about the dangers of food poisoning.

Government & Industry coordination

Other departments, including Agriculture Canada and Environment Canada, co-ordinate their programs of food poisoning prevention with Health and Welfare Canada in those areas where the departments' interests overlap. Cooperation among these federal departments, the provincial and municipal governments, and members of Canada's food industry helps to ensure that the food Canadians buy is free of contaminants which might lead to food poisoning.

PREVENTATIVE MEASURES FOR CONSUMERS

The federal government can only go so far in protecting Canadians against the hazards of food poisoning. In the home, food safety is *YOUR* responsibility. Assuming that most foods are free of contamination when you get them, it's up to you to keep

them safe until they are served. Remember, the two keys to preventing food poisoning are *sanitation* and *temperature control*.

Sanitation: Employ sanitary food handling practices. When preparing food, keep yourself, your utensils, and your work area clean to limit the contamination of one food from another. Especially clean all surfaces that have contacted raw poultry. Keep all cuts clean and covered. Keep your work area free of flies and other insects which might spread bacteria. Don't handle food if you have a cold; if you must sneeze or cough, cover your mouth.

Temperature control: Keep foods in which bacteria grow rapidly out of the **DANGER ZONE** (40° — 140° F or 4° — 60° C). Potentially unsafe foods which provide an especially good medium for bacterial growth (such as meat, poultry and fish dishes, stuffing, gravies, meat and potato salads, custards and puddings, eggs, and cream-filled desserts) deserve special attention. Such foods should be thoroughly cooked and kept hot (above 140° F internally) or refrigerated (below 40° F internally) until serving.

REFERENCES

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Materials Available from Educational Services, Health Protection Branch

Aflatoxin Analyses for Consumer Protection — Dispatch #26

Barbecue Chicken and Food Safety — Tear Sheet

The Can With a Story — Tear Sheet

Danger Zone in the Kitchen — Programmed Learning Booklet

Food Safety — It's All in Your Hands — Booklet

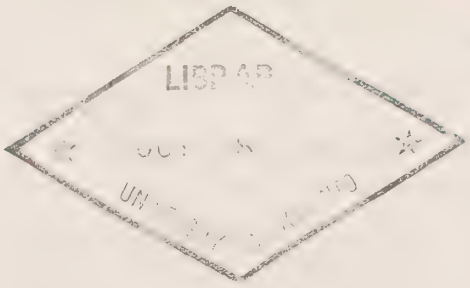
The Danger Zone — Poster

Available from Visual Education, Toronto

Food — Handle With Care — Slide Series

Health and Welfare Canada
Santé et Bien-être social Canada

NO 33
DATE August 1974



CANADIAN DRUG LAWS AND THE CONSUMER

The Health Protection Branch of Health and Welfare Canada is responsible for monitoring the potency, purity, and safety of Canadian drug products through the administration and enforcement of three Federal statutes: the *Food and Drugs Act*, the *Proprietary or Patent Medicine Act* (PPM Act) and the *Narcotic Control Act* (see the appendix to this Dispatch for brief descriptions of each act).

From the viewpoint of the Canadian consumer, these laws divide drugs into three major categories:

1) Over-the-counter (OTC) drugs

2) Prescription drugs

3) Restricted and prohibited drugs

Over-the-Counter Drugs

Over-the-counter drugs are medicinal preparations intended for self-medication which may be purchased without a prescription. Many common products such as headache remedies, antacids, cough medicines, laxatives, etc., fall into this category of drugs. The manufacture, labelling, advertising and sale of OTC drugs are regulated by provisions of the *Food and Drugs Act and Regulations*, the *Proprietary or Patent Medicine Act*, or the *Narcotic Control Act*.

It is not always easy for a consumer to determine what constitutes an OTC drug. For example, vitamin and mineral preparations, while perhaps not thought of as drugs by many consumers, are considered to be drugs according to both the *Food and Drugs Act* and the *PPM Act*. Synthetic vitamin and mineral preparations are generally sold as over-the-counter drugs, but preparations containing more than 10,000 International Units (I.U.) of vitamin A or 1,000 I.U. of vitamin D may be obtained only on prescription.

It may also surprise consumers to know that, although most cosmetic products do not fall under the official definition of "drug", cosmetic preparations which make claims of a medical nature, such as a product claiming to contain "medicinal ingredients which help to heal acne blemishes", are classified as drugs and are subject to the provisions concerning drugs. Most cosmetic drugs are available over-the-counter.

Many drugs which are available only on prescription for human use, like certain potent antibiotics, may be sold over-the-counter as veterinary drugs providing the drug is in a form not suitable for human use and the product carries the statement "For Veterinary Use Only" on the label.

Educational Services, Health Protection Branch

dispatch

	FOOD & DRUGS ACT & REGULATIONS	*PROPRIETARY OR PATENT MEDICINE ACT*	*NARCOTIC CONTROL ACT & REGULATIONS*
Date Act Came into Effect	1920	1909	1961
Historical Precedent	Adulteration Act 1884	None	Opium Act 1908
Drugs Defined in the Act	*Drug* — "any substance or mixture of substances manufactured, sold or represented for use in: a) the diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state, or the symptoms thereof, in man or animal; b) restoring, correcting or modifying organic functions in man or animal; or, c) disinfection in premises in which food is manufactured, prepared or kept, or for the control of vermin in such premises".	*Proprietary or patent medicine* — "every artificial remedy or prescription manufactured for the internal or external use of man, the name, composition or definition of which is not to be found in. . .any foreign pharmacopoeia approved by the Minister,. . .or any formulary adopted by any properly constituted pharmaceutical association representing Canada and approved by the Minister; or upon which is not printed in a conspicuous manner the true formula or list of medicinal ingredients contained in it".	*Narcotic* — "any substance included in the (Narcotic) Schedule or anything that contains any substance included in the Schedule".
Types of Drugs Regulated by the Act	Pharmacopoeial drugs sold over-the-counter, prescription and controlled drugs (Schedules F of the Regulations, G of the Act), restricted (Schedule H of the Act) and prohibited drugs	Proprietary or patent medicines sold over-the-counter	Narcotic drugs
Major Purposes or Provisions of the Act and/or its Regulations	. *Conditions of sale* — the sale of drugs which have been adulterated or have been manufactured, prepared, preserved, packaged or stored under unsanitary conditions is prohibited; *Deception* — deceptive practices in the labelling, packaging, treatment, processing or advertising of drugs is prohibited; . *Standards* — both "trade" and "professed" standards regarding the manufacture and sale of drugs are described; . *Sample distribution* — distribution of samples permitted only to physicians, dentists, veterinary surgeons, or pharmacists under specific conditions; . *Prohibited advertising* — drugs purported to treat, prevent, or cure any of the diseases, disorders, or abnormal states listed in Schedule A may not be advertised to the public; . *Controlled sales* — thalidomide may not be sold; Schedule F (of the Regulations) and G (of the Act) drugs may be sold only on prescription; . *Inspection* — drug inspectors have the power to examine anything in a drug plant at any reasonable time. . *Importation* — specifications for governing, regulating, or prohibiting the importation, distribution or sale in Canada of any drugs manufactured outside of Canada are given; . *New drugs* — procedures to be followed for the introduction of new drugs to the Canadian market are outlined.	. *Registration, review and approval* of the formula for each proprietary preparation before marketing; . *Annual review and licensing* of each registered formula; . *Quantitative declaration* on the label of any ingredients which are listed in the PPM Schedule (hazardous and/or potent drugs); . *Prohibition* of false, misleading or exaggerated advertising; . *Efficacy* for claims made, and prohibition of the claim that any PPM product will "cure" any condition; . *Sample distribution* to members of the general public prohibited; . *Maximum limits* of alcoholic content and dosage of PPM Schedule drugs fixed by a non-government Advisory Board of experts in pharmacology and medicine.	*Purposes* of the Act are: . *To control* the legitimate use of narcotic drugs on the domestic market through a licensing system of manufacturers, wholesalers, and dealers; . *To suppress* domestic illicit trafficking in narcotic drugs with the cooperation of the RCMP; . *To cooperate* with the United Nations in suppressing international illicit trafficking in narcotic drugs.

Prescription Drugs

Prescription drugs are those which may legally be obtained only on prescription from a practicing physician, dentist, or veterinary surgeon. Many drugs which were over-the-counter drugs at one time have become prescription drugs, because it was found they were likely to be misused or abused by members of the general public, or that they could produce injury in a substantial number of users. By taking the control of such drugs out of the hands of consumers, the government eliminates the temptation of people to use them indiscriminately without medical advice.

The manufacture and sale of prescription drugs are controlled through the *Food and Drugs Act* and the *Narcotic Control Act*. Drugs which are designated as prescription drugs are listed in Schedule F of the *Food and Drug Regulations*, Schedule G of the *Food and Drugs Act*, and the Narcotic Schedule of the *Narcotic Control Act*.

Schedule F of the *Food and Drug Regulations* lists most of the drugs commonly prescribed by physicians including antibiotics, sedatives, tranquilizers and contraceptive drugs. As in other Schedules of the Regulations, the drugs are listed generically, so that a few pages of generic listings account for several thousand brand name products.

Controlled drugs are drugs which, in addition to being available to consumers only on prescription like Schedule F drugs, are also restricted at the manufacturing and distribution levels by being available only from firms licensed by the government to deal in them. Controlled drugs are listed in Schedule G of the *Food and Drugs Act* which contains mostly amphetamines, barbiturates and their salts and derivatives. Schedule G came into effect in 1961 when diversion and misuse of barbiturates and amphetamines were high and demanded special legislative controls. While regulated very stringently, Schedule G drugs have not been put under the jurisdiction of the *Narcotic Control Act*. However, anyone who violates the provisions of the *Food and Drugs Act* by trafficking in Schedule G drugs or possessing them for the purposes of trafficking is guilty of an offense punishable by a maximum penalty of 10 years imprisonment.

Prescription drugs listed in the Schedule of the *Narcotic Control Act* include certain "preparations, derivatives, salts and similar synthetic substances" of the opium poppy (opium, codeine, morphine, etc.), coca (cocaine), cannabis sativa (marihuana), and numerous other lesser known drugs. Under the *Narcotic Control Act*, possession of any drug listed in the Schedule is legal only if the possessor is a licensed dealer, a practicing physician or veterinarian, a pharmacist, a hospital, a person who obtained the drug on prescription, or a person authorized by the Minister of National Health & Welfare or in the *Narcotic Regulations*.

Unauthorized possession of a narcotic drug is a criminal offense which may result in a summary conviction (maximum penalty of $2,000 and/or 1 year imprisonment) or conviction on indictment (maximum penalty of 7 years imprisonment). Trafficking in narcotic drugs or possession for the purposes of trafficking may result in life imprisonment. The actual penalties imposed for possession of narcotics depend upon the drug involved, the exact nature of the charge, and the judgement of the court. First offenders are normally treated more leniently than habitual traffickers.

Restricted and Prohibited Drugs

Restricted drugs are those which are not available to the consuming public at all. They are listed in Schedule H (formerly Schedule J) of the *Food and Drugs Act* and include drugs which are recognized as being very potent but whose properties and effects are not yet well established, such as lysergic acid diethylamide (LSD); N,N-diethyltryptamine (DET);N, N-diemthyltryptamine (DMT); 4-methyl 2, 5-dimethoxyamphetamine (STP), 3, 4-methylenedioxyamphetamine (MDA) and a number of other extremely potent drugs.

Drugs on the restricted list are considered to be so dangerous that their possession is authorized only for licensed dealers, qualified investigators (for research purposes), official analysts, inspectors, RCMP and other peace officers, and persons appointed by the Minister. Such drugs, obviously,

should not be taken lightly and deserve the precautionary measures which surround them as restricted drugs. However, though they are highly dangerous and susceptible to abuse, research with these drugs is important to determine if they can be useful tools of medicine.

Unauthorized possession of a restricted drug is punishable by a maximum penalty of $2,000 and/or 1 year imprisonment upon summary conviction and $5,000 and/or 3 years imprisonment upon conviction on indictment. Trafficking or possession for the purposes of trafficking is punishable by a maximum of ten years imprisonment.

A prohibited drug is one known to be so dangerous and detrimental in its effects on man that its manufacture, sale, distribution and use are strictly forbidden. It is not available to anyone, at any time, for any purpose. The only drug presently prohibited in Canada is thalidomide, which tragically caused malformations several years ago in the fetuses of mothers who had taken the drug during pregnancy.

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Narcotic Control Act and Regulations, with Amendments to November 3, 1970.

Proprietary of Patent Medicine Act, with Amendments to January 31, 1966.

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Health and Welfare Canada
Santé et Bien-être social Canada

NO 34
DATE October 1974

A CAUSE FOR COMPLAINT

The Johnsons came over that night for their weekly bridge game, and Mrs. Barrister served crackers with cheese and meat spread. The game went well and everyone enjoyed the evening, but the next day, both couples were victims of vomiting, diarrhea, headaches, and weakness. When Mr. Barrister also developed double vision and difficulty in swallowing, Mrs. Barrister knew this was no ordinary flu. She called the family doctor who advised both couples to come to the hospital immediately.

At the same time, on the other side of the city, an inspector in the regional office of the Health Protection Branch received a call from Mrs. Ralston who told him about the swollen appearance of a tin of meat she had purchased and was about to feed to her children for lunch. The inspector told her he would come to collect the tin right away and instructed her not to open it. As he was leaving for the Ralstons, the inspector got a call from the Barristers' doctor at the hospital who alerted him to four possible cases of food poisoning.

Tests conducted by the hospital and the Health Protection Branch revealed that the Barristers and Johnsons had been the victims of botulism, the deadliest form of food poisoning known to man. Mrs. Barrister and Mrs. Ralston had purchased the same brand of meat paste, and when the Branch labs analysed the swollen can obtained from Mrs. Ralston, the presence of Clostridium botulinum toxin was confirmed.

Armed with this information, the Health Protection Branch put into motion an elaborate and complex mechanism designed to prevent further incidence of botulism caused by the contaminated meat paste.

First, the Branch inspector contacted the firm that had marketed the meat and put the contaminated lot under suspension. He then notified the manufacturer who quickly initiated a total recall all across Canada. Further tests uncovered botulinum contamination in at least three different lots of the product, due to underprocessing at the plant.

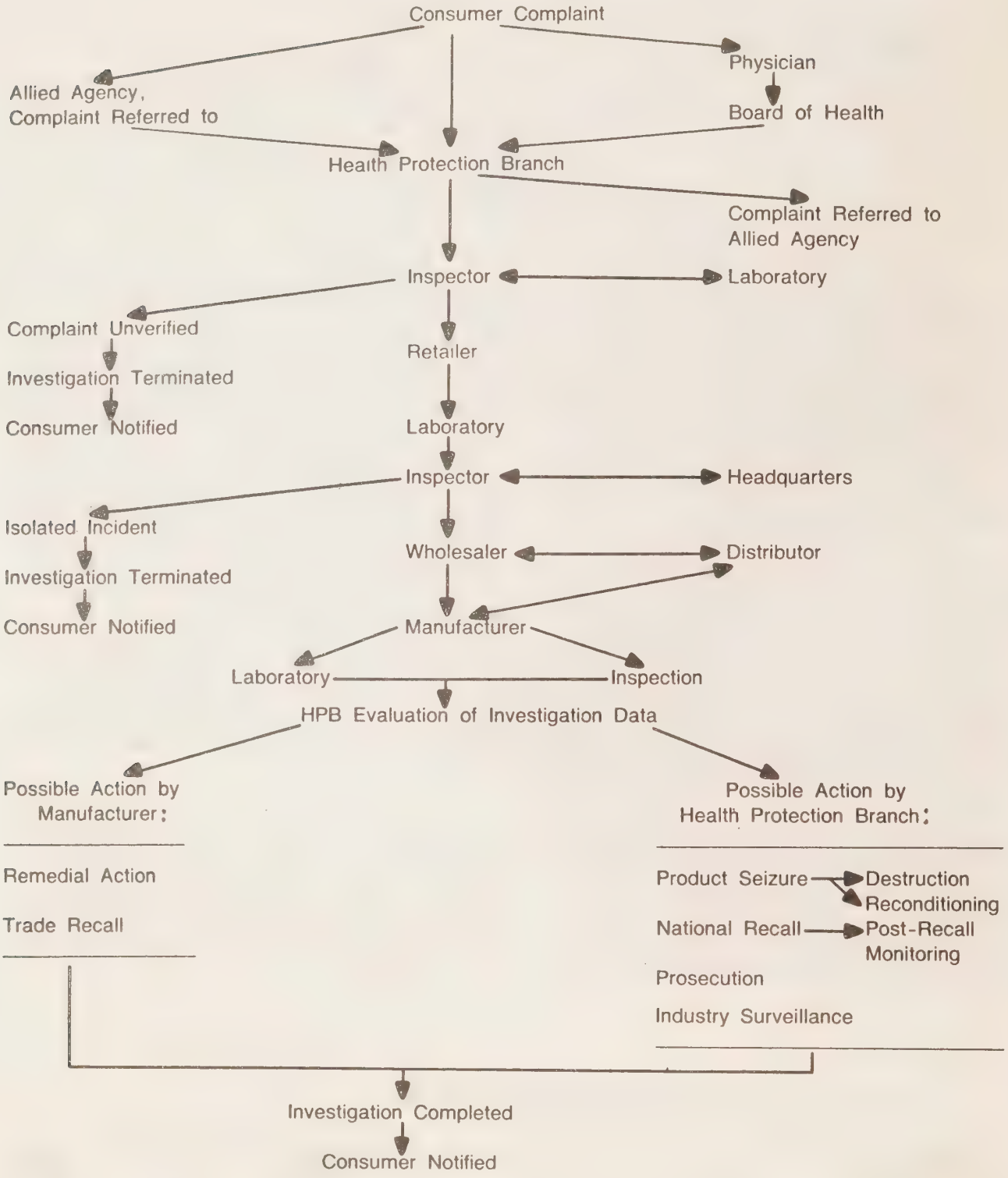
Working through the media, the Branch lost no time in alerting Canadians to the danger of botulism and, with the complete cooperation of the firm involved, the Branch was able to have most of the product removed from grocers' shelves and destroyed within three days.

As a follow-up measure, the manufacturer undertook remedial action to improve quality control and inspection to prevent a recurrence of the food poisoning incident. Fortunately, the Johnsons and Barristers were the only people who had eaten the contaminated meat paste, and because of the swift treatment they received, all four recovered completely within weeks.

Educational Services, Health Protection Branch

dispatch

PATH OF AN HPB INVESTIGATION



The above story is fictitious. It didn't happen, but it could have. During 1973 alone, the Health Protection Branch received many complaints from consumers who felt that a particular food had made them ill. Although most of the cases turned out to be food allergies rather than actual food poisoning, the 20% that were verified probably saved other Canadians from experiencing the unpleasant, and sometimes dangerous, effects of food-borne illness.

Every year, thousands of Canadians lodge complaints with the Health Protection Branch about foods, drugs, cosmetics, or medical devices which they believe are harmful in some way. These people are not chronic complainers. For the most part, they are responsible citizens who report their concerns about products to protect others.

If you purchase a food which makes you sick when you eat it, or a drug which causes an unexpected reaction when you take it, reporting the problem is the only way to launch an investigation through federal authorities.

Complaint Procedure

The nature of your complaint will determine the authority you should contact. The Health Protection Branch has jurisdiction over all aspects of the manufacturing, labelling and advertising of drugs, cosmetics, and medical devices. Complaints arising from adverse reactions, misleading advertising, mislabelling, or illegal sale of these products should be directed to your local inspector in the nearest district or regional office of the Health Protection Branch. It's true that your adverse reaction may just be a personal allergy, or that what you thought was misleading advertising is annoying but legal; however, if there is even the slightest possibility of deception or danger, the product should be reported so that it can be investigated by federal experts.

The responsibility for complaints involving foods is divided among several federal and provincial departments. If you get ill from food eaten in a restaurant or feel that the food is served in unsanitary surroundings, you should report your dissatisfaction to your regional or municipal health unit. If your community does not have a local health unit, contact your provincial department of health.

Complaints involving the safety and quality of processed foods (packaged, frozen, canned or bottled) are handled by the Health Protection Branch. If you buy a processed food which smells, looks or tastes strange, is mouldy, or contains foreign matter, contact your local HPB inspector. Complaints about fresh foods may be made either to the Health Protection Branch or to the departments having jurisdiction over those foods. The Department of Agriculture has responsibility for complaints involving fresh meats and fruits, and the Department of Fisheries handles complaints about fresh fish.

Any complaint involving food advertising or fraud is dealt with by the Department of Consumer and Corporate Affairs. CCA also handles all consumer complaints involving hazardous products other than food, drugs, cosmetics and medical devices.

Path of an HPB Investigation

As you can see from the accompanying chart, when a complaint reaches the Health Protection Branch, either directly from a consumer or by referral from another agency, a complex string of events is set in motion to insure the removal of the dangerous or defective product from the Canadian marketplace.

At the time of your initial contact with the HPB inspector, he will ask you a number of questions about your complaint. Your name and address will be kept confidential if you wish, but other information you give will determine who handles your complaint.

If the product you are complaining about is not the responsibility of HPB, the inspector will refer you to the proper authority. However, if your complaint does fall under the jurisdiction of the Health Protection Branch, a full investigation will be carried out by the inspector — including sending a sample of the suspected product to the nearest HPB laboratory for analysis.

If preliminary analysis confirms a possible health hazard, the inspector will obtain additional samples at the retail outlet where the product was purchased. If further laboratory analysis proves the product is contaminated or defective in some way, the firms which manufacture and market the product will be contacted and asked to suspend distribution and sale until further investigation can determine the

scope and seriousness of the problem. If the threat to health is sufficiently serious, the manufacturer may be asked to issue a voluntary recall to remove the product from public sale. In extreme cases, such as outbreaks of botulism, the Branch may issue a public warning through the media concurrent with a national emergency recall.

In the event of either a voluntary or national emergency recall, follow-up surveillance in the form of post-recall monitoring of the manufacturer's premises will ensure that the health hazard has been eliminated.

Whether a consumer's complaint results in the withdrawal of one item or a national recall of the entire inventory of a product, he will be notified by the inspector as to the outcome of his complaint.

Complaint Statistics

The Health Protection Branch handles a large volume of consumer complaints. As the following table shows, the number of complaints has more than doubled in the last ten years. This increase doesn't mean that our food, drug and cosmetic industries are getting slacker; it means that consumers are becoming more aware of their own role in health protection.

SUMMARY OF COMPLAINTS

	1963			1973		
	V*	NV*	Total	V*	NV*	Total
Food	620	638	1258	2337	342	2679
Drugs	38	61	99	112	100	212
Cosmetics	9	26	35	14	60	74
TOTAL	667	726	1392	2463	502	2965

*V — Verified Complaint, ie. complaint against product justified.

NV — Non-verified Complaint, ie. product was satisfactory or evidence against inconclusive.

The nature of the complaints received by HPB depends on the type of product. Complaints about food may involve such things as: chemical contamination, foreign matter, food-borne illness, or organoleptic problems (smells, looks, or tastes "off").

Drug and cosmetic complaints are generally concerned with adverse reactions in which the product doesn't work at all or causes some unexpected physical manifestations. Some drug and cosmetic complaints involve mislabelling and misleading advertising.

Medical device complaints can range from non-sterility of supposedly sterile products such as syringes to defective products such as artificial limbs which malfunction.

As you can see, your involvement in health protection is important. If you ever believe that a particular product poses a threat to health, then you have "a cause for complaint" and should report your concern to the authorities.

REFERENCES

Daniels, W.F., "The Health Protection Branch Investigational Approach", presented at the Workshop on Food Poisoning, Ottawa, April 1974.

Food and Drugs Act and Regulations, with Amendments to March 26, 1974.

"Food Safety", Part 2, *Food in Canada,* May 1973.

Health and Welfare Canada
Santé et Bien-être social Canada

NO 35
DATE November 1974

SECOND REPORT ON ORAL CONTRACEPTIVES

In 1970, a special committee of seven Canadian physicians appointed by the Minister of National Health and Welfare published its first report on "All Aspects of the Safety and Efficacy of Oral Contraceptives Marketed in Canada". In its second report, issued this past summer, the committee records progress on recommendations made in 1970 and lists many new recommendations expected to be enacted in the near future.

Some of the recommendations made in the first report which have since been acted upon are summarized below:

Dosage

Recommendations advising physicians to prescribe contraceptive preparations containing "the lowest dose of each component compatible with maximum effectiveness" have been endorsed, and physicians are now prescribing mainly the combined oral contraceptive preparations containing reduced amounts of estrogen.

Product Testing, Research & Surveillance

The Health Protection Branch has enforced recommendations for extensive animal toxicity studies, using several animal species, to be carried out before a new oral contraceptive is put on the market; contraceptive preparations already on the market are continually monitored by the Health Protection Branch through the Drug Adverse Reaction Reporting Program. In addition, research grants have been provided by government agencies to individuals and groups for clinical, epidemiological, and basic scientific studies on oral contraceptive preparations.

Information to the Professions and the Public

For professionals, current developments in the field of oral contraceptives are periodically published in the *Rx Bulletin*, and detailed updated information on individual products is available from the manufacturers in a Product Monograph. For the public, an agreement has been reached with the manufacturers to include consumer-oriented information in a package insert with each oral contraceptive product.

After reporting on the progress made in enforcing recommendations from the earlier report, the updated second report details more than 30 additional recommendations concerning oral contraceptives. Some of those recommendations are quoted below:

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Duration of Use:

"The Committee believes that healthy women may continue oral contraception for several years providing they have good medical supervision and exhibit no complications or significant side effects. In adolescents with unproven fertility and a history of functional ovulatory cycles, it would be prudent to stop oral contraceptives after 2 years to permit spontaneous ovulation and menstruation to occur, before resuming medication".

Risk of Thromboembolism

"There is an urgent need for epidemiologic studies in healthy women to clarify the relationship between estrogen dosage and the incidence of serious thromboembolic complications. Present information is inadequate to assess the risk of postoperative thromboembolism in women taking oral contraceptives . . . There is no single test or series of tests that could be reasonably applied, prior to prescribing an oral contraceptive, to screen out patients who have a special risk of venous thrombosis. Further studies should be directed towards finding such a test or tests".

Carcinogenesis

"The possible carcinogenic effect of oral contraceptives is incompletely understood and continued observations are required . . . Particular attention should be directed to the development of carcinoma of the breast, because estrogens have induced breast cancer in experimental animals and probably also in human males given large amounts for a prolonged time".

Depression

"The Committee recommends that well controlled long term clinical trials be designed to study emotional reactions related to oral contraceptive therapy".

Hypertension

"Oral contraceptives may aggravate hypertension or precipitate its onset . . . Until reliable predictive criteria are established, one should be wary of using oral contraceptives in patients with previous toxemia and hypertension during pregnancy, renal disease, or a strong family history of hypertension".

Risk of Abnormal Pregnancy

"The use of an oral contraceptive within 6 months prior to conception may be associated with an increased incidence of lethal developmental and chromosomal anomalies in the conceptus (ie., fatal abnormalities in the embryo) . . . Both anomalies will result in abortion prior to 3 months gestation (i.e., before 3 months of pregnancy). There is no evidence at all that babies born to mothers who have used an oral contraceptive are at greater risk to developmental anomalies than those born to mothers who have not. However, women should await the resumption of ovulatory cycles before attempting to become pregnant".

Post-coital Contraception

"The use of diethylstilbestrol (DES) for post-coital contraception has caused concern . . . The Committee feels that if the mode of use and the warnings outlined in this report are recognized, post-coital therapy is justifiable in selected 'emergency' situations and should reduce the number of therapeutic abortions and their complications . . . The Committee condemns post-coital contraception as a method of choice. Other methods are definitely preferable".

Follow-up of Marketed Products

"Special attention is required in two areas: the effects of long term usage (5 years and more) and the effects on teenagers . . . questions should be answered —

Is there a limit to the number of years a patient may safely take oral contraceptives?" The report goes on to ask: Does such a time limit, if it exists, vary according to the age of the woman and the number of children she has had? Does long-term use of an oral contraceptive produce any bodily changes not found with short-term use, and does withdrawal from the medication after long-term use produce any changes?

Following the new recommendations, the Committee's second report contains detailed discussions of information which led to the recommendations on post-coital contraception, low dosage progestogens, indications for altering or discontinuing medication, specific problems associated with the use of oral contraceptives, oral contraceptives and drug interactions, assessment of risks, information to the professions (in the Product Monograph), and information to the public (in the package insert).

Generally speaking, this second report seems to reinforce implications made in the first report that, while oral contraceptives certainly have an important role to play in controlling the growth of the world's population, their use involves many potential risks and unknown effects which must be further researched and assessed before a blanket statement can be made affirming or denying the safety and efficacy of oral contraceptives marketed in Canada.

A review of the highlights of the second report of oral contraceptives may be found in the Summer 1974 issue of the *Rx Bulletin*, (Vol. 5 No. 3) published by the Health Protection Branch and available from Information Canada. The complete report can also be obtained from Information Canada at a minimal cost.

REFERENCES

Educational Services, "Items From the Report on Oral Contraceptives", Dispatch #9, December, 1970.

"Oral Contraceptives Reviewed", *Rx Bulletin*, Vol. 5, #3, Summer 1974.

Health and Welfare Canada
Santé et Bien-être social Canada

NO 36
DATE Winter 1974-75

A CENTURY OF HEALTH PROTECTION

This year marks the 100th anniversary of Canadian federal health protection. A century ago, the cornerstone was laid when Parliament passed the *Inland Revenue Act of 1875* "to impose license duties on compounders of spirits; to amend the act respecting inland revenue; and to prevent the adulteration of food, drink, and drugs". The responsibilities inherent in that first law have greatly expanded over the years. Today, the Health Protection Branch (HPB) carries out a multi-faceted health protection program on several fronts.

HPB's primary purposes are: to protect Canadians from harmful foods, drugs, cosmetics, medical devices, and radiation emitting devices; to control fraudulent practices concerning drugs and medical devices; to determine the possible adverse effects of environmental factors on health; to investigate the causes and cures of communicable and non-communicable diseases; to collect and distribute data on the health and disease status of Canadians; and to engage in informational activities, research, and funding of community projects intended to prevent harmful use of alcohol, tobacco, and illicit drugs and to remedy the consequences of such use.

These objectives are achieved through the administration of three basic pieces of legislation: the *Food and Drugs Act and Regulations*, the *Radiation Emitting Devices Act and Regulations*, and the *Narcotic Control Act and Regulations*. A bill introduced into the Senate provides for the repeal of a fourth act, the *Proprietary or Patent Medicine Act*, to become effective on January 1, 1976, and the drugs covered by the act to be regulated in the future through a separate division added to the *Food and Drug Regulations*.

In the current organizational structure, the Health Protection Branch is composed of seven directorates, Administration plus six activity-oriented bodies:

FOOD DIRECTORATE

The Food Directorate is responsible for branch programs relating to wholesomeness, nutritional quality, chemical and biological hazards in the food supply, and for programs relating to the nutritional status of Canadians. It conducts research on nutrition, food composition, food additives, pesticides, veterinary drug and environmental contaminants in foods; updates and promulgates food standards and regulations; and evaluates submissions from food manufacturers.

DRUGS DIRECTORATE

Through the application of the *Narcotic Control Act and Regulations* and those portions of the *Food and Drugs Act and Regulations* referring to drugs and cosmetics, the Drugs Directorate is responsible for programs relating to the safety, purity and effectiveness of drugs on the Canadian market and for programs relating to the safety of cosmetics.

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The directorate monitors the manufacture, marketing, distribution, and advertising of drugs and engages in continual research on drug quality, toxicity, pharmacology and bioavailability.

ENVIRONMENTAL HEALTH DIRECTORATE

The Environmental Health Directorate is concerned with environmental safety. A wide range of investigative research and advisory programs is carried out within the directorate to study various technological environments which can affect the health risks arising from air and water-borne pollutants, and to assess the effectiveness and safety of various medical and radiation emitting devices. The directorate is responsible for the enforcement of the *Radiation Emitting Devices Act* and that part of the *Food and Drugs Act* dealing with medical devices and radiopharmaceuticals.

LABORATORY CENTRE FOR DISEASE CONTROL

The Laboratory Centre for Disease Control (LCDC) is the health surveillance arm of the Health Protection Branch. The centre collects and distributes information on the national health and disease status of the Canadian population in order to facilitate the prevention and control of disease, disability, and death. LCDC also provides a national reference laboratory service for the identification and control of disease producing bacteria, viruses, and parasites. It also conducts work to provide corrective information to meet the new and changing hazards arising from technological and sociological stresses and the accelerating rate of change in these stresses.

NON-MEDICAL USE OF DRUGS DIRECTORATE

Problems arising from the use of tobacco, alcohol, and illicit drugs fall within the functional scope of the Non-Medical Use of Drugs Directorate. The directorate supports research into the nature and effects of drug abuse, and funds programs in prevention, treatment, and rehabilitation such as service-oriented street clinics and youth projects. Drug education and information programs, and training and development programs for professionals in the field, are also carried out by the directorate.

FIELD OPERATIONS DIRECTORATE

The Field Operations Directorate is responsible for the reduction of health hazards which the public may be exposed to through the importation, manufacture, advertisement or sale of marketed foods, drugs, cosmetics, medical devices and radiation emitting devices. This is accomplished through regulatory actions such as: inspections of the premises of food, drug and cosmetic manufacturers, importers, distributors and retailers; analytical surveys of finished products to check for the presence of contaminants and for compliance with federal standards; investigations of consumer product complaints; and enforcement actions.

Within the directorate, Educational Services explains branch activities and interprets branch policy to the public and acts as the liaison between consumers and the Health Protection Branch. Through this two-way avenue of communication, HPB is made aware of consumer health concerns and is able to keep Canadians up to date on what the Health Protection Branch is doing about them.

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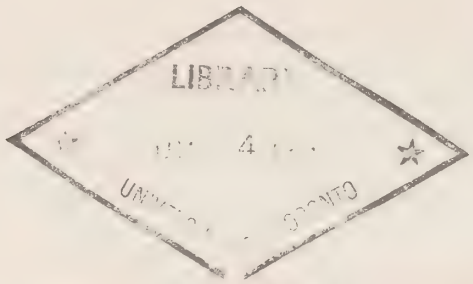
NO 37
DATE Spring 1975



NUTRITION CANADA PROVINCIAL, INDIAN, AND ESKIMO REPORTS

In November 1973, Health and Welfare Canada published the general findings of the Nutrition Canada Survey in the *Nutrition Canada National Survey* report. Since then, detailed analysis of the data obtained in the survey has permitted the release of twelve further reports–ten provincial reports and two separate reports on Indians and Eskimos. These in-depth studies represent completion of the second stage in analysis of Nutrition Canada Survey data. Later, special reports dealing with dental health, eating habits and anthropometry will be published.

The provincial, Indian, and Eskimo reports give detailed information about the nutrient intakes and the biochemical and clinical findings of the groups involved. Few interprovincial differences are revealed in these reports, but Indians and Eskimos have several nutritional problems not found in other groups.

Brief summaries of the findings in the provincial, Indian, and Eskimo reports are given below.

WEIGHT

The detailed reports reaffirm the high prevalence of overweight in adult Canadians of all provinces. The overweight problem, and extreme obesity in a significant number of adults, is prevalent in groups, such as females over 65, having very modest calorie intakes. This finding indicates that a better balance between energy intake and expenditure is necessary throughout life to prevent obesity.

IRON

Although the incidence if iron deficiency anemia is low, the provincial reports give evidence that substantial numbers of women, adolescents, infants and children have marginal or inadequate iron intakes and low iron stores.

PROTEIN

The national survey report had suggested a protein deficiency in pregnant women, but detailed examination of the data has shown this observation to be incorrect. In fact, the protein intakes of all age groups seem to be satisfactory, though the protein status of the elderly in some provinces was just marginally adequate.

CALCIUM and VITAMIN D

The calcium intakes of provincial populations are satisfactory for most groups, but the median intake values for teenage girls generally fall into the marginal range between adequate and inadequate intakes. The median values for pregnant women, except in British Columbia, are also marginal, indicative of the need for increased consumption of calcium-rich foods, such as milk and cheese, by this group. Differences in milk consumption are probably responsible for the observed regional and provincial variations in calcium intakes. The calcium intakes of some groups in Newfoundland are the highest in the

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country, partly attributable to the mandatory fortification of flour with calcium in that province. Sample groups in the other Atlantic provinces also tend to have higher median calcium intakes than those in the rest of Canada, while some groups in Quebec have the lowest.

Although the vitamin D intakes are low for some groups across the provinces, there is little clinical evidence of rickets, perhaps because exposure to sunlight provides additional vitamin D to most Canadians. The vitamin D intakes of the elderly, many of whom are confined indoors for long periods, could be improved through increased consumption of dairy products.

VITAMIN C

The median vitamin C intakes of all groups in the provinces are adequate, although some of the elderly are at high risk according to serum vitamin C levels. There is evidence of bleeding gums in many adults of the 20-29 year-old group, but it is not clear whether this condition is due to a vitamin C deficiency or to periodontal disease.

VITAMIN A

The vitamin A status of most Canadians examined in the provincial surveys is adequate, although the median intakes of middle-aged and elderly females are close to the marginal range.

THIAMIN, RIBOFLAVIN, and NIACIN

The thiamin, riboflavin, and niacin intakes of most groups surveyed in the provinces are adequate, although the median intakes in groups which consume relatively small amounts of food, such as middle-aged and elderly women, are lower than median intakes for other groups. Some small interprovincial differences in the median intakes of these vitamins are noticeable; for example, the median thiamin intakes in Newfoundland are unusually high, while niacin intakes in that same province are consistently low. Also, the median intakes of both thiamin and riboflavin in Quebec are lower than median intakes of those nutrients in other provinces.

FOLIC ACID

The provincial reports reinforce the finding of the national survey that many Canadians have low serum folate values. The clinical significance of this observation is not known, but Canadians should be encouraged to include in their diets sources of folic acid such as green vegetables and liver.

IODINE and THYROID SIZE

There are significant regional variations in the incidence of thyroid enlargement. In the prairie provinces, British Columbia, and Newfoundland, goitre is evident in all groups beyond pre-school age. The occurrence of thyroid enlargement is lowest in New Brunswick, P.E.I., Quebec, and Ontario. Curiously, the appearance of thyroid enlargement in the sample groups does not seem to be related to iodine intake, and further research will be necessary to discover what is causing this condition in the presence of adequate iodine intake.

INDIANS and ESKIMOS

The special reports on Indians and Eskimos reveal that Indians share the general population's overweight problem and both groups have low iron stores like the rest of the sample groups. Furthermore, the Indians and Eskimos have additional nutritional problems which are not apparent in other Canadians. Both ethnic groups have low calcium and apparently low vitamin D intakes; in fact, the estimated vitamin D intakes of Eskimos are so low that rickets may soon become a common condition among Eskimo children. Furthermore, Eskimos and many Indians living in remote areas are classified as high risk regarding vitamin C status. The prevalence of bleeding gums in these groups, particularly in Eskimos, suggests the presence of vitamin C deficiency. The vitamin A status of Eskimos and Indians is also a cause for concern; the vitamin A intakes of Eskimos are especially low.

Taken together, the provincial, Indian and Eskimo surveys indicate that, although most Canadians consume a nutritious diet, some segments of the population have inadequate intakes of certain nutrients. In order to maintain, and improve upon, our

present nutritional status, programs involving nutrition must be implemented. Steps are already underway to introduce legislation designed to enrich selected foodstuffs, and to generate nutrition education programs which will acquaint Canadians with their nutritional needs.

REFERENCES

Educational Services, *Nutrition Canada National Survey Report*, Dispatch 29, December 1973.

Health and Welfare Canada, *Nutrition Canada Ontario Survey*, Summaries, chapters V-XIV (repeated in all the provincial, Indian, and Eskimo reports), 1975.

Copies of the Nutrition Canada provincial, Eskimo, and Indian reports are available to the public from Information Canada bookstores in Halifax, Montreal, Ottawa, Toronto, Winnipeg, and Vancouver. They may also be purchased at a cost of $5.75 each by writing to:

Information Canada
171 Slater Street
Ottawa, Ontario
K1A OS9

When ordering any of the reports by mail, enclose a cheque or money order for the full amount made payable to the Receiver General of Canada.

Dispatch No. 40

Cosmetic Safety and the Consumer

Cosmetics are a part of everyone's daily grooming routine. From the newborn's baby powder to grandpa's after-shave lotion. Estimated sales of cosmetics in Canada total over one billion dollars annually.

Regardless of whether the product is a beauty preparation (make-up, perfume, skin cream, nail polish) or a grooming aid (toothpaste, soap, shampoo, deodorant), all cosmetics sold to consumers must meet the requirements of the Food and Drugs Act and Cosmetic Regulations and the Consumer Packaging and Labelling Act and Regulations.

Cosmetic or Drug?

The law defines a cosmetic as a product which cleanses, improves or alters the complexion, skin, hair or teeth. A beauty product or grooming aid is usually categorized as a cosmetic, but will be legally classified as a drug if it makes any claims to modify body functions, to prevent or treat disease.

Here are some examples:

- A toothpaste is a cosmetic when it cleans, whitens and brightens the teeth. It is a drug when the special ingredient is added which will prevent tooth decay.
- A deodorant is a cosmetic because it acts to control odour in perspiration on the skin's surface. An antiperspirant is a drug because it suppresses the flow of perspiration to the skin's surface.

What Safety Criteria Must a Cosmetic Meet?

The Food and Drugs Act and the Cosmetic Regulations set safety requirements. All cosmetics sold in Canada must be:

- free from filth, foreign matter and substances that may injure the health of the user when the cosmetic is used according to label directions or customary ways of use;
- manufactured, prepared, preserved, packed and stored under sanitary conditions; and
- on notification with the government as to their composition. (A manufacturer must disclose the composition of any cosmetic so that the acceptability of its ingredients can be monitored. If a safety concern arises, the cosmetic is prohibited from the market. These "trade secrets" are considered as confidential.)

How Reliable Are Manufacturer Claims and Advertisements?

Claims for a cosmetic on a label or in an advertisement must be accurate so that they do not mislead the public. Since certain claims, such as increased attractiveness or increased masculinity, can only be judged subjectively, some puffery (exaggeration of a kind which does not mislead the public) is tolerated.

The Canadian Broadcasting Act requires that any radio or television advertising of cosmetics must be previewed and cleared by the Health Protection Branch before it can be broadcasted. Printed advertisements do not require pre-clearance review. Instead, a selection of popular Canadian magazines and newspapers are monitored and if an advertisement does not conform with the Regulations, the advertiser is asked to change or withdraw it.

What Information Must Be on Cosmetic Labels?

Labelling is regulated by the Food and Drugs Act, the Cosmetic Regulations and the Consumer Packaging and Labelling Act and Regulations.

To comply with these requirements, cosmetic labels must supply:

- the identity of the product, in English and French in terms of common or generic name or function;
- a statement of net quantity in metric units of measurement;
- the name and address of the manufacturer or distributor; and

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Western
3155 Willingdon Green
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V5G 4P2

Central
510 Lagimodière Blvd
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R2J 3Y1

Ontario
2301 Midland Ave.
Scarborough, Ontario
M1P 4R7

Quebec
1001 St-Laurent St. W.
Longueuil, Quebec
J4K 1C7

Atlantic
5th Floor, Ralston Building
1557 Hollis Street
Halifax, Nova Scotia
B3J 1V5

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– directions, warnings or cautions, in English and French where necessary for safe use of the product.

Specific regulations also exist for the safe use of special products, such as hair dyes. In addition, the statutes prohibit false and misleading representation or deceptive packaging.

How Are Hair Colours Labelled?

Permanent and semi-permanent hair dyes, which employ coal tar dye bases and coal tar dye intermediates to produce the colour, are required by law to also carry on their labels:

– a warning that the product may cause skin irritation on certain individuals;

– a warning not to use the product for dyeing eyebrows and eyelashes because to do so may cause blindness; and

– instructions for carrying out a preliminary test for skin irritation called the **patch test**.

What Is the Patch Test?

The patch test is a way of determining an individual's sensitivity to products, including cosmetics.

To make the test, a small area of the skin behind the ear or upon the inner surface of the forearm is cleansed, then a small quantity of the cosmetic as prepared for use is applied to the area and allowed to dry. After 24 hours, the area is washed gently with soap and water.

If there is any redness, burning, itching, blistering or eruptions, the reaction is positive and the cosmetic should not be used.

The patch test should be performed whenever permanent or semi-permanent hair dyes are used. Sensitivity to these ingredients may not reveal itself until after these products have been used a number of times and therefore the patch test should be repeated before each application.

Other types of hair dyes are sold in Canada and these do not require routine use of the patch test because they do not cause skin irritations in most persons.

Are Hair Dyes Safe?

The Food and Drugs Act requires that cosmetics be safe under the intended condition of use. The Health Protection Branch's evaluation of current scientific data indicates there is no hazard associated with the proper use of hair dyes.

Are Hair Conditioners Necessary?

Modern shampoos contain "surface active" substances which are very efficient at removing grease, dirt and perspiration from the hair. Depending on individual hair characteristics (normal, oily, dry), shampoos can leave some users with very little natural oil on the hair and this can result in the hair becoming dry, brittle or developing split-ends.

Conditioners provide a thin coating to the outer surface of the hair strand which helps retain moisture in the hair even after rinsing. Conditioners with "natural" ingredients such as vitamin E or henna, do not necessarily convey any special benefits to the product.

Also, in cleansing the hair, some shampoos will leave the hair dull-looking, susceptible to tangles and static electricity. Some conditioners therefore, contain ingredients which will make the hair lustrous and manageable. Conditioners can also protect the hair from damage that can arise from frequent use of permanents.

How Safe Are Eye Cosmetics?

The Cosmetic Regulations under the Food and Drugs Act prohibit the use of coal tar dyes or coal tar dye bases or coal tar dye intermediates, in products for use in the "area of the eye".

This prohibition applies to all eye make-up including eyebrow and eyelash colours.

In addition, eye cosmetics must meet the same requirements as other cosmetics regarding safety and sanitary manufacturing.

The Branch has an ongoing monitoring program on bacterial contamination of cosmetics especially eye products. Random samples at the wholesale and retail levels are examined to determine if products contain bacteria which could cause an infection. If contamination is found, the sale of such a product is discontinued until corrective action is taken by the manufacturer.

However, part of the responsibility for safety from microbiological contamination belongs to the individual consumer. In the area of eye cosmetics, much depends on the way the product is handled after purchase.

Since infection of eye tissue can have very serious consequences, possibly even blindness, always follow these basic safety precautions:

– Wash your hands before applying eye cosmetics.

– Never use saliva to moisten mascara or other eye make-up.

– Never borrow or share eye make-up.

– Discontinue the use of an eye cosmetic **immediately** if its use results in irritation or inflammation.

What Are Hypoallergenic Cosmetics?

"Hypoallergenic" is neither a legal nor a scientific term. It simply means that the manufacturer has selected ingredients with the objective of producing a finished product with minimum potential for causing allergy. There are no nonallergenic cosmetics.

If you experience an allergic reaction to a cosmetic, try switching to a different brand.

Are Tanning Products Cosmetics?

Suntan lotions, **oils** or **creams** are considered cosmetics. They help the user to stay out longer in the sun and thereby increase the opportunity for the user to get a tan. The suitability of a particular product is dependent on the individual's melanin (dark pigment) production. Many of these products also help in moisturizing the skin.

Sun blocks or **screens**, however, are considered drugs because the product claims to prevent sunburn by shielding the skin from the sun's ultraviolet radiation.

Topical tanning products play an important role in protecting the skin from the sun's radiation. However, it must be remembered that excessive exposure to the sun can cause skin damage, skin cancer and eye damage. Also certain medications, including antibiotics and diuretics, can increase an individual's sensitivity to the sun.

Oral tanning products are also drugs since they are ingested. These synthetic colouring agents, often identical to natural ones, are taken in large amounts so that the extra colouring agents become stored in the body's fatty tissue including tissue under the skin. These oral products do not provide a "sun" tan nor do they provide any protection from the sun's radiation. The "tan" will fade if the product is discontinued and as the colouring agents are eliminated from the body.

Natural Versus Synthetic

There is an assumption on the part of many consumers that a natural product is better -- healthier -- than a similar synthetic one. However, in some natural products, the natural ingredient may be preserved by synthetic additives or be no different in its chemical composition from a synthetic one.

Although many natural products are sold, there is no scientific proof that the natural ingredients convey any special advantages to the product. In fact, often a synthetic ingredient which mimics a natural one, provides a purer, more stable ingredient which may give the product a longer, usable life.

The principal health concern with natural products lies in the possibility of bacterial contamination. The products may not contain a preservative so that the natural ingredients may spoil if not stored properly.

The Branch considers natural ingredients in cosmetics to have no particular advantage over synthetic ones.

What to Do if an Adverse Reaction Is Suspected

If an adverse reaction is suspected, discontinue the use of the cosmetic. Consult a general practitioner or dermatologist for advice and treatment if the reaction is severe or prolonged and remind the physician to report the problem to the Health Protection Branch. If a physician is not needed, notify the Branch yourself of any unusual or injurious reactions by telephoning the local Branch office or by writing to:

Cosmetics Division
Bureau of Nonprescription Drugs
Health Protection Branch
Department of National Health and Welfare
Vanier, Ontario, K1A 1B8

Be sure to include the following information:

– your name, address and telephone number in case additional information is required;

– the product brand name and product type, and any descriptive information such as cream, spray, cologne, etc.;

– the name and address of the manufacturer as it appears on the label and any lot or code number;

– how long and how often you used the product;

– a description of the adverse reaction you experienced, including whether the reaction occurred while you were applying the product or whether it developed some time after application;

– whether you have consulted a physician about the problem;

– and treatment and outcome of the reaction.

By reporting adverse reactions to cosmetics, consumers will be helping the Branch identify worrisome products and indicate where corrective action may be required.

The Consumer and Cosmetic Safety

Laws and regulations provide the consumer with an increasing degree of protection, but cannot prevent misuse of cosmetics by the consumer. It is extremely important to read and follow exactly any directions for use provided by

the cosmetic product. This information is provided to assist the user in avoiding potential hazards and is a vital factor in the safe use of cosmetics.

It is also important to remember that:

- cosmetics should not be shared with someone else as there is the possibility of cross-contamination by skin bacteria;
- cosmetics should not be stored for a long time (over one year) since the product's properties may alter with age and no longer be as satisfactory; and
- cosmetics should be kept out of the reach of children to avoid accidental ingestion.

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Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"La sécurité en matière de cosmétiques"

Cat. No. H49-46/2-1990E
ISBN 0-662-17420-8

Health and Welfare Canada
Santé et Bien-être social Canada

HA DP
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NO 41
DATE Summer 1976

BOTULISM AND HOME CANNING

In Canada last year, four people died after eating improperly prepared marine products. They were victims of the deadliest form of food poisoning known to man, *BOTULISM*. Though it is extremely rare, botulism strikes several Canadians every year. There have been a few cases of botulism due to inadequately processed commercially prepared foods, but most outbreaks are associated with home prepared foods which have been improperly preserved, stored under anaerobic (in the absence of oxygen) conditions, and consumed without appropriate heating.

WHAT IS BOTULISM?

Botulism is a food-borne illness or food intoxication caused by the spore-forming micro-organism, *Clostridium botulinum*. This bacteria and its spores are found everywhere; in the soil, on raw fruits and vegetables, and on meat and fish. The spores are the inactive form of the bacteria and are very resistant to adverse conditions, such as heat and chemical treatment, that normally will destroy the actively growing micro-organism. However, in low-acid food, under anaerobic conditions, the botulinum spores become active, begin to grow, and produce a toxin or poisonous substance. If a food becomes contaminated and is eaten without sufficient heat treatment to destroy the toxin, severe illness and, in many cases, death can occur.

Botulism is a tragic and poorly understood disease. It differs from other types of bacterial-caused food poisoning, in that it affects the nervous system rather than the digestive tract.

HOW DOES IT OCCUR?

Botulinum toxin can occur in low-acid canned or processed foods whenever inadequate heating or processing permits spore survival. Conditions which contribute to the development of toxin are:

- lack of air, as in a sealed can, jar, or plastic package.
- foods which contain little or no added acid: some examples are meat, poultry, fish, seafood, mushrooms, eggs and most vegetables; chili peppers, cucumbers and certain varieties of tomatoes have only a medium acid content and should be treated with care.
- temperatures between 4°C (40°F) and 46°C (115°F). Growth of the spores is fastest at about 38°C (100°F).

If these conditions are present and adequate precautions are not taken, botulinum spores can germinate and produce a toxin so potent that one cupful of the pure toxin, it is estimated, could kill the entire population of the world.

Sometimes cans or jars with food containing botulinum toxin will bulge or have off odours, but this

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doesn't always happen. It is not uncommon for a botulinum-contaminated food to appear and smell normal.

Frozen or dried foods and those with high concentrations of acid, salt or sugar do not support the growth of botulinum bacteria and are therefore usually quite safe to eat.

SYMPTOMS OF BOTULISM POISONING

The early signs of botulism – fatigue, weakness and blurred vision – usually develop about 8 to 72 hours after eating food containing botulinum toxin. These symptoms are followed by laboured breathing, difficulty in speaking clearly, dizziness, headaches, abdominal discomfort, vomiting and muscle paralysis. Botulism is difficult to diagnose because of its rare occurrence and the similarity of its symptoms to many other illnesses. An antitoxin does exist, but it should be given as soon as possible and is not always completely effective.

HEALTH PROTECTION BRANCH CONTROL

Under the authority of the Food and Drugs Act and Regulations, the Health Protection Branch of Health and Welfare Canada regulates the manufacture and distribution of food products sold in Canada. General provisions in the Act make it possible for the Branch to exercise control over the spread of pathogenic micro-organisms. Several regulations deal specifically with the problem of *C.botulinum.* Some examples are:

- Fish – smoked fish or smoked fish products which are packed in containers sealed to exclude air must be heat processed after sealing at a temperature and for a time sufficient to destroy *C.botulinum.*

- Meat – meats packed in hermetically sealed containers must be heat processed to prevent the survival of any toxin-producing micro-organisms. Meats which are not heat treated in this way must be subjected to further processing such as freezing, dehydration, or the addition of preservatives or an acid medium.

In addition to legislation the Health Protection Branch plays a major role in inspection, research and education to ensure a safe food supply for Canadians.

BOTULISM REFERENCE CENTRE

Recently, the work of the Botulism Reference Centre for Canada has come under the responsibility of the Health Protection Branch. This centre provides several important services such as investigating cases of food poisoning where botulism is suspected, alerting responsible agencies when a commercially produced food is involved, accumulating information on botulism, and maintaining reference cultures and supplies of antitoxin.

Whenever botulism is suspected, you should contact your physician or local health unit immediately so that they can alert the Botulism Reference Centre, and if necessary commence treatment.

PREVENTIVE MEASURES FOR CONSUMERS

As a consumer, food safety in the home is YOUR responsibility. To guard against botulism, follow these simple preventive guidelines:

Commercially Prepared Foods

- Never use or even taste canned foods that show any sign of spoilage. Bulging can ends and jar lids usually indicate spoilage. When you open the container, check for off odours, froth, foam or mold.

- When a commercially prepared food is involved, a large number of people may be at risk; therefore, report any suspect food to ycur local public health authorities or the Health Protection Branch.

Home Canned Foods

- Always follow recommended canning procedures (See NOTE).

- All vegetables, meat, and fish must be processed in a pressure canner. Boiling temperatures are insufficient to destroy all the bacterial spores in these foods. Meat and fish are particularly susceptible to the growth of botulinum bacteria; they are not recommended for home canning.

- Check containers and contents before using the food. If there are any signs of spoilage, do not taste it. **THROW IT OUT.**
- Often there may be no signs of spoilage. As an extra measure of safety, it is a wise precaution to boil home canned vegetables for 10 minutes before tasting.
- A reminder: canned fruits, jams and jellies, and pickles and relishes do not cause botulism; high concentrations of acid, salt or sugar prevent the growth of botulinum bacteria.

NOTE: Agriculture Canada's booklet "Canning Canadian Fruits and Vegetables", #1560 may be obtained by writing the Information Division, Agriculture Canada, Ottawa K1A 0C7

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Material Available from Educational Services, Health Protection Branch

The Can With A Story – Tear sheet

Danger Zone In the Kitchen – Programmed learning booklet

Food Safety – It's All in Your Hands – Booklet

Food Poisoning – Leaflet

The Danger Zone – Poster

Available from Visual Education Centre, 115 Berkeley Street, Toronto, Ontario M5A 2W8

Food-Handle With Care – Slide Series.

Health and Welfare Canada
Santé et Bien-être social Canada

NO 42
DATE Fall 1976

THE COST OF TRANQUILITY

Canadians live in a world of constant social change and technological advance. Over the past quarter-century, many have come to accept the idea of chemical relief from the stresses and strains of modern living. Perhaps we have gone too far with our "pill for every ill" philosophy, and the time has come to examine our routine reliance on chemical remedies. Coping with everyday life without a "chemical crutch" is necessary and desirable for good health and mental maturity.

Evidence of our over-dependence on chemical cure-alls can be seen in the growing misuse of the class of drugs referred to as tranquilizers, or anxiety-relief agents.

What are tranquilizers?

Tranquilizers are drugs which act on a person's emotional state, calming him without affecting his consciousness or thought processes. They are used extensively to treat emotional disorders characterized by excessive anxiety and tension. Tranquilizers concern us because they are subject to abuse and can cause both physical and psychological dependence when used for too long a period of time, or in doses exceeding the prescribed dosage.

How do tranquilizers work?

In normal doses, they usually relieve abnormal tension and anxiety. Many tranquilizers also are used to treat convulsive disorders and withdrawal symptoms of alcohol dependence.

Common products in the tranquilizer market include diazepam (Valium, Vivol), chlordiazepoxide (Librium, Protensin, Solium, Via-Quil), meprobamate (Equanil, Miltown), oxazepam (Serax), and clorazepate (Tranxene).

Who controls tranquilizers?

In Canada, the manufacture and distribution of tranquilizers are controlled by the Health Protection Branch of Health and Welfare Canada, through administration of the **Food and Drugs Act and Regulations.**

Tranquilizers (which come in a variety of dosage forms including tablets, capsules, syrups, and solutions for injection) may be sold only upon written or verbal prescription by a licenced physician.

Are there side effects?

As with any other drug, some individuals may experience undesirable side effects when using tranquilizers. Drowsiness is the most commonly reported side effect, and it may be especially dangerous to people who drive or operate machinery while using tranquilizers. Other possible adverse reactions include dizziness, depression, rashes and nausea.

Combining tranquilizers with any other drugs may potentiate or interfere with the actions of the tranquilizers. Most tranquilizer poisonings involve excessive use of other

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drugs or alcohol. Because it has been well documented that an individual's tolerance for alcohol decreases when a tranquilizer is taken concurrently, persons taking tranquilizers should never consume alcohol at the same time.

Tranquilizers and women of childbearing age

Tranquilizers should not be used during pregnancy, particularly during the first three months, unless in the opinion of your physician the potential benefits outweigh the possible hazards to the fetus. If you are using a tranquilizer and become or intend to become pregnant, consult your physician.

Hazards of tranquilizer misuse

The rising popularity of tranquilizers is disturbing. Since their introduction in the 1950's, these products have become the most widely prescribed group of drugs in Canada today, as well as a leading cause of poisoning (as reported to Canada's Poison Control Centres). Statistics show that enough tranquilizers are sold in this country every year to keep over a quarter of a million Canadians in a constant state of "tranquility".

Since the use of tranquilizers is so prevalent, it's important for consumers to be aware of the hazards involved with tranquilizer misuse. The most common hazard is **psychological dependence**. It is present when you feel you **need** tranquilizers just to get through the day. Relying on tranquilizers as an all-purpose answer to everyday problems is a dangerous habit to get into.

A less common though more serious problem is **physical dependence**. With the regular use of prescribed tranquilizers, your body develops a tolerance, so that you may be tempted to increase the daily dosage to maintain the desired effect. **Never exceed the dosage prescribed by your physician.**

What's the solution to tranquilizer misuse?

Let's take steps to cut down on tranquilizer misuse by reducing reliance on drugs. Most of life's problems can be solved without resorting to chemical intervention. Stop and think about it.

What's your drug dependency potential?

Check your attitudes towards drug use in general and tranquilizers in particular by answering the following questions:

- Do I reach for a tranquilizer every time anxiety, nervousness, or tension appear?
- Do I ignore instructions about the maximum number of tablets or capsules that may be taken at any one time, or during one day, and often exceed this recommended limit?
- Do I pressure my physician for a tranquilizer prescription to relieve nervous tension, insomnia, or other indefinite symptoms when I know that my problems are personal rather than medical?
- Do I request renewal of my prescription beyond the period for which my physician strictly recommended I use the tranquilizer?
- Is my medicine chest a mini-drugstore of prescriptions or over-the-counter medications for "nerves", sleeplessness, tension, aches and pains?
- Do I feel cheated if I leave my physician's office without a prescription after each and every visit?

If the answer is "yes" to most of these questions, you may have crossed the line from occasional, justified use of drugs to excessive reliance on chemical crutches.

Watch out for the danger signs and avoid the pitfalls of overuse and misuse of drugs. Remember, the cost of chemically-induced tranquility can be high.

Dispatch No. 44

Sunlamps and Tanning Facilities: A Burning Issue

An estimated 2000 persons are treated for sunlamp burns or eye damage every year in the emergency departments of Canadian hospitals. These people were too eager to obtain a tan quickly. They either stayed under a sunlamp or in a tanning facility too long, positioned themselves too close to the lamp or did not wear goggles to protect their eyes. Many fell asleep and were harmed by excess radiation from the ultraviolet lamps.

The radiation responsible for these injuries is ultraviolet radiation, which is also found in sunlight. Ultraviolet (UV) radiation is similar in characteristics to visible light, but is of higher frequency and shorter wavelength.

Ultraviolet radiation is divided into three ranges of wavelengths (A,B,C) and is measured in nanometres. One nanometre is equal to one-billionth (10^{-9}) of a metre.

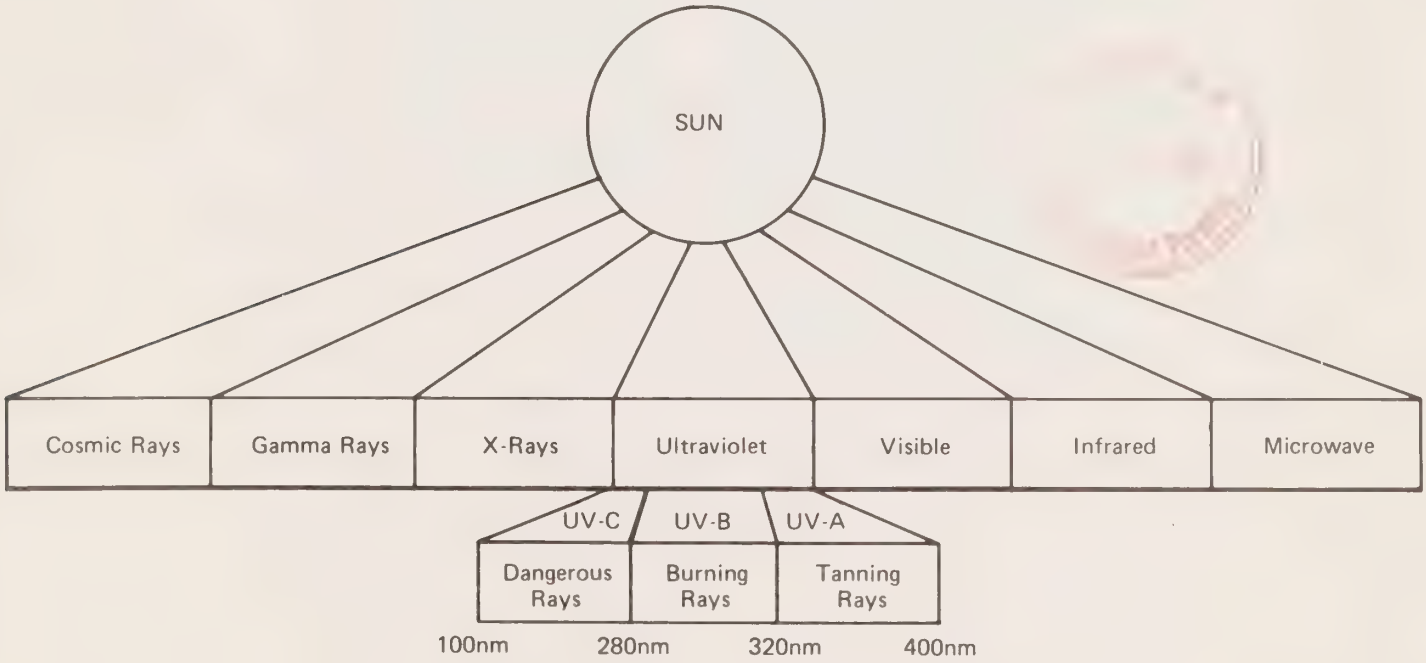

Figure 1. Spectrum of the earth's electromagnetic radiation.

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Atlantic
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1557 Hollis Street
Halifax, Nova Scotia
B3J 1V5

Health and Welfare Canada
Santé et Bien-être social Canada
Canada

Radiation	Range	Characteristics
UV-A	longwave 320-400 nm	most innocuous, darkens pigment immediately, interacts with certain drugs and cosmetics causing sensitivity to the skin
UV-B	medium wave 280-320 nm	blamed for sunburns, causes delayed pigment darkening, absorbed by window glass
UV-C	shortwave 100-280 nm	most energetic and dangerous to humans, emitted by the sun but absorbed by the atmosphere before reaching the earth

Figure 2. Types of ultraviolet radiation and their effects on humans.

The UV-C radiation normally found in sunlight is absorbed by the ozone layer in the atmosphere and does not affect humans. However, some types of sunlamps produce UV-C along with UV-A or UV-B radiation. Since UV-C radiation is considered potentially carcinogenic and hazardous to humans, federal regulations restrict UV-C emissions in sunlamps to a minimal level. UV-A is largely responsible for causing immediate pigment darkening while delayed tanning results from UV-B radiation. There is a concern about UV-A radiation when it is combined with the ingestion of certain drugs which can cause photosensitive or photoallergic reactions in humans.

Since the popular commercial tanning facilities are equipped with ultraviolet lamps, they can produce the same kind of damaging effects to the skin, eyes and body chemistry as domestic sunlamps.

Skin Damage

When the skin is exposed to excessive amounts of UV radiation, it becomes red and with prolonged exposure, it burns. Ultraviolet radiation can also cause the destruction of cells in the outer layers of the skin and alterations in cell structure.

Extensive UV exposure is the principal cause of premature skin aging. Severe or repeated exposure (even without burning) can cause permanent damage, which may not become obvious for several years. After such exposure, the skin loses its elasticity and becomes wrinkled; in other words, it ages. There is evidence to suggest that in some cases, the end result of long-term exposure is skin cancer.

Very fair-skinned individuals with freckles and blond or red hair are particularly susceptible to injury from UV radiation because their melanin-producing capacity is limited. Melanin is the dark brown or black pigment that gives the skin a tan. It is produced by cells in the underlying layers of the skin; when these cells are activated by UV, they increase their production of melanin, which gradually moves to the outer layers. The resulting tan absorbs the UV radiation, thus protecting the inner layers from further injury. Individuals with limited melanin-producing capacity do not develop the same degree of protection and are more likely to sustain skin damage by prolonged sunlamp exposure. Usually less than 15 minutes exposure to direct midday sunlight in midsummer can cause sunburn in fair-skinned individuals. Sunlamps can cause a burn in a much shorter time because the intensity of UV can be greater than in sunlight.

Eye Injury

The eyes are also very susceptible to the harmful effects of UV radiation. Two extremely painful, but usually temporary, conditions known as *photokeratitis* and *conjunctivitis* can result from looking at a sunlamp directly for even a few seconds. Symptoms of these conditions are pain, a feeling of sand in the eye (or the impression of looking through gauze), and a higher sensitivity to bright light (photophobia). When the eye is subjected to intense or chronic exposure to UV radiation, *corneal opacity* and *cataract* of the eye lens may develop, causing loss of vision. Severe burns to the eye can even scar the cornea and produce a permanent impairment of vision.

Sensitizing Chemicals

The use of certain drugs can enhance an individual's sensitivity to UV radiation from sunlight or sunlamps. This enhanced sensitivity is used successfully in the treatment of psoriasis. UV-A activates the molecules of psoralen, a drug ingested by the patient before exposure. This action leads to a reduction in skin-cell proliferation in the areas exposed to UV radiation. However, an inadvertent increase in sensitivity to UV-A radiation can occur with the following drugs and agents:

- sulfas;
- diuretics (drugs which rid the body of excess fluid) and drugs for the treatment of high blood pressure containing diuretics (e.g. hydrochlorothiazide);
- certain antibiotics (e.g. tetracyclines);
- estrogens (used for the treatment of menopause and other gynecological problems);
- tranquilizers containing phenothiazine derivatives;
- griseofulvin (for treatment of ringworm);

- sulfonylurea-containing drugs or oral hypoglycemic agents used in treatment of diabetes;
- diseases causing photosensitivity such as lupus erythematosus, pemphigus, pemphigoid, dermatomyositis, porphyria, granuloma annulare, acne rosacea, albinism and vitiligo.

Cosmetic ingredients (in perfumes, deodorants, soaps) may react with UV radiation to produce photoallergic or phototoxic effects (e.g. redness, itching, hives, blistering or uneven pigmentation). It is wise not to apply these products to the exposed skin before tanning. If in doubt about a particular chemical's potential effect in relation to UV exposure, consult a physician, the "Compendium of Pharmaceuticals and Specialities" or the Health Protection Branch.

Government Controls

The Health Protection Branch has monitored the use of domestic sunlamps for some time and has been concerned about the high levels of UV-C emitted from these devices. Federal regulations on sunlamps were promulgated under the Radiation Emitting Devices Act in July 1980. These permit manufacturers to produce sunlamps that only emit a minimal level of UV-C radiation.

The present sunlamp regulations also require manufacturers to ensure that:

- the sunlamp is equipped with a timer that will shut off the lamp automatically after a preset time interval;
- goggles or other protective eyewear are supplied with the sunlamp;
- the sunlamp is clearly marked with a warning that its use can lead to burns and other types of injuries;
- instructions for safe use accompany the sunlamp.

Sunlamps

Three types of sunlamps were on the market prior to the 1980 regulations (Figure 3). One of these types, which has a reflector (Type III) is no longer considered safe and it is recommended that consumers avoid using it

Type I is shaped like a floodlight and can be screwed into the domestic-type lamp socket. This sunlamp has a *reflector* built into the lamp, but may not be equipped with a timer. It may also produce UV-C and UV-B radiation.

Type II looks like an ordinary *fluorescent* lamp and is often used in health spas and tanning facilities. It produces predominantly UV-B and UV-A radiation. These prefabricated cubicles, rooms or beds may have one or more sunlamps located in various positions (Figure 4).

Both these sunlamp types have a special coating on the inside surface of the glass envelope to help reduce UV-C radiation, which contributes little to the tanning process, but causes more severe injury than UV-B or UV-A radiation. The special lamp coating produces a similar effect to that of the ozone layer in the earth's atmosphere by filtering out the hazardous wavelengths.

Type III uses a bare mercury lamp incorporated into a separate *reflector* housing. Although this type is often equipped with a timer, the bare mercury lamp does not have the special coating and may emit hazardous levels of UV-C radiation. It should not be used.

Type I

Type III

Figure 3. Two different types of reflector sunlamps.

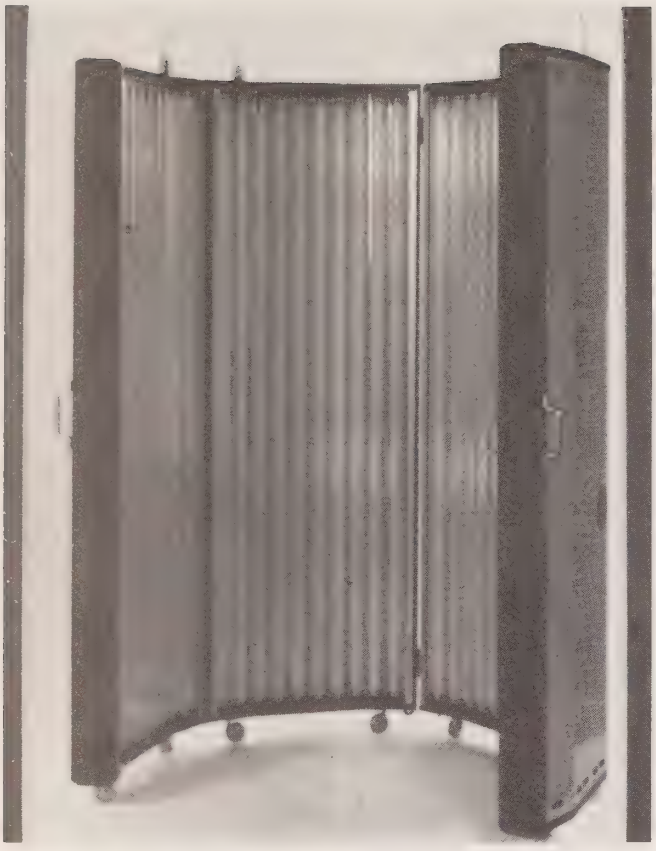

Figure 4. Tanning booth with Type II fluorescent lamps.

Tanning Facilities

Ongoing monitoring by the Branch of the record of injuries in Canada indicates that injuries are resulting from commercial tanning facilities. Consequently, equipment recommendations for tanning facility operations will be incorporated as amendments to the sunlamp regulations.

These recommendations for tanning facilities relate to:

- user positioning - proper exposure distance must be maintained;
- time error - only 10 percent inaccuracy range allowed;
- protective eyewear - must be provided to user;
- temperature control - booth must not be warmer than 38°C (100°F).

There are also equipment recommendations regarding electrical safety, mechanical construction, protective lamp barriers, and design considerations for emergency entrance and exit.

Precautions for the Photosensitive

The hazards from exposure of healthy individuals to UV-A lamps appear to be minimal. However, the possibility of photosensitive reactions due to the combination of certain drugs and UV-A radiation is of major concern.

Some individuals may be at risk using a sunlamp or commercial tanning facility if they:

- sunburn easily and do not tan;
- have severe sunburn or chronically damaged skin;
- get frequent cold sores (UV radiation may aggravate this condition);
- take any photosensitizing drugs or have a disease causing photosensitivity. (See sensitizing chemicals section.)

When a sunlamp is prescribed to treat medical problems, your physician has determined that the benefits outweigh the long-term risks. But when you decide *on your own* to use a sunlamp, you must decide whether the benefits outweigh the risks.

Safety Precautions

Regulations alone cannot protect persons against misuse of the sunlamp at home or in a tanning facility. To protect yourself, follow the simple precautions below:

- Do not wear any cosmetic preparations while tanning.
- Do not shower or take a sauna before tanning because when you towel dry, you remove some of the natural protective body oils.
- Wear goggles or other protective eyewear before turning the lamp on. Do not under any circumstance look at an operating sunlamp without suitable eye protection.
- Always follow the manufacturer's instructions with regard to the distance, exposure time and frequency of exposure. If there are no instructions accompanying the sunlamp, obtain advice from the manufacturer before use.
- Always use the automatic timer to set the exposure time according to the manufacturer's recommendations. If your sunlamp at home does not have a timer, use a separate timer that will give a loud signal at the termination of the preset time interval. The timer should be started the instant the lamp is switched on. Do not tamper with the timer while tanning.
- Commence the exposure schedule with a short exposure time and gradually increase the time for subsequent exposure. This procedure will help build up the melanin protection against injury to the skin.

- If you notice any immediate reddening of the skin, discontinue exposure at once. The tanning effect should not be visible for at least a few hours after exposure.

If you require further information about sunlamps or commercial tanning facilities, contact the Non-Ionizing Radiation Section, Bureau of Radiation and Medical Devices, Health and Welfare Canada, Ottawa K1A 0L2.

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Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"Lampes solaires et salons de bronzage: Une question brûlante"

Cat. No. H49-46/7-1990E
ISBN: 0-662-17425-9

Dispatch No. 46

Infant Feeding

Increased knowledge about the benefits of breast-feeding and about the nutritional needs of infants has brought about changes in infant feeding practices. The trend now is for parents to feed babies as nature intended, which means that more women -- now over three-quarters of all new mothers -- are choosing to breast-feed their infants. And, they're breast-feeding their babies for longer periods than women have in recent decades.

Once infants are weaned from the breast, many are now given an infant formula instead of cow's milk, and the trend in feeding solid foods is to withhold solids until infants are four months of age or older. Many families are choosing to prepare their own infant foods at home.

Because there are so many choices available in infant feeding practices, some confusion exists as to which are preferable and why. Health professionals and consumers alike need accurate information on infant foods, whether these are to be used as the total diet for an infant or to serve as supplements.

Breast-feeding

The slogan used by health care professionals is "breast-fed is best-fed" which indicates that breast milk is the best source of nutrition for infants up to the age of six months.

There are many advantages to breast-feeding, the most important of which is that human breast milk contains the ideal mix of nutrients for optimum growth and development in the human infant. The amino acid composition is well-suited to the metabolic needs of the infant, and the fat, carbohydrate, vitamins and minerals in breast milk are very well absorbed. In addition, breast-fed babies seem better able to resist infections during the early months of life when their own immune system is immature. They seem particularly resistant to respiratory and gastrointestinal infections, and less prone to allergic responses such as eczema.

On the practical side, breast-feeding is economical, requiring only a slight increase in the nursing mother's intake of food energy; convenient as there are no bottles to sterilize, the milk is always ready at a right temperature and safe since there can be no errors or danger of contamination in mixing the milk.

Supplementation

Supplementation of the nursing mother's diet should not be necessary providing she eats a well-balanced diet which includes one litre of vitamin-D-fortified milk or its equivalent daily. Nursing women who do not eat any animal products should take vitamin B_{12} supplements. Some physicians may however recommend that a woman continue taking prenatal supplemental vitamins and mineral nutrients during the nursing period.

The Canadian Paediatric Society and Health and Welfare Canada recommend that vitamin D supplements be given to all breast-fed infants. Breast-fed infants whose mothers consume no animal products should receive a daily vitamin B_{12} supplement.

The infant who is totally breast-fed does not need additional dietary iron until about six months of age. However, if the breast-fed infant is given solids before six months, he should receive an additional dietary source of iron, such as iron-fortified infant cereal, by four months.

Fluoride

Fluoride has been shown in studies to reduce the incidence of dental caries or tooth decay; in North America, fluoride is obtained from naturally or artificially fluoridated water. There is no evidence to show, however, that breast-fed infants require fluoride supplementation, even though the amount of fluoride in breast milk is very small. Some infant formulas contain fluoride, so consumers are advised to check with their family doctor or pediatrician after their baby is weaned from the breast regarding the need for fluoride supplements in their area.

Other Concerns

Breast-feeding is a highly portable method of feeding a baby; if a mother is not always available for feeding or if she chooses to return to work outside the home, breast milk may

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Santé et Bien-être social Canada

Canada

be expressed and stored in plastic bottle liners or sterilized jars. Each container should hold only enough for a single feed. Breast milk will keep in the refrigerator for up to 48 hours. Breast milk can also be frozen in the refrigerator freezer for up to 2 months or in a deep freezer at -20° C for up to 6 months. To thaw frozen breast milk, put the container under cold then warm running water or set in a pan of warm water for approximately five minutes. Breast milk should not be allowed to stand and thaw at room temperature. Shake the milk to distribute the fat particles evenly and serve at once.

Many drugs or chemicals taken by the nursing mother will pass to the baby through the breast milk; this includes alcohol, nicotine and non-prescription as well as prescription drugs. For this reason, women who are breast-feeding should be cautioned against using any drugs, smoking or drinking and they should consult with their family doctor or pediatrician in the event that drugs are required.

There has been some concern in recent years about certain environmental contaminants being found in milk, specifically DDT and PCBs (polychlorinated biphenyls). It is true that very small amounts of these chemicals have been found in samples of breast milk in women living in certain areas; DDT levels have decreased since restrictions on this chemical were imposed in 1969. PCBs are now closely controlled as well, but certain bodies of water in Canada, such as the Great Lakes, are considered contaminated; it is therefore recommended that women of child-bearing age or who are nursing infants not eat fish from these waters. Consumers are advised to check with their provincial or territorial government about specific regulations or recommendations in their area.

Infant Formulas

Commercially prepared formulas (or breast milk substitutes) are the next best thing to breast milk and are used when breast milk is not available or when a woman chooses not to nurse her infant. Formulas are available in several forms: Powdered concentrate, which is mixed with cooled boiled water before serving; liquid concentrate which is mixed with cooled boiled water; and ready-to-serve, which is available in cans.

Nutrient Content

Commercial infant formulas are formulated to resemble the nutrient composition of breast milk and are a more satisfactory substitute for breast milk than any other product. Infant formulas are generally based on either cow's milk or soy protein and contain a mixture of vegetable oils which provide essential fatty acids and which are better absorbed than butterfat. Lactose is the most common source of carbohydrate in milk-based formulas whereas those based on soy usually contain sugar or corn syrup solids. Infant formulas sold in Canada must meet specific requirements of the Food and Drug Regulations which were promulgated in 1976 to control the nutritional composition of these formulas and to ensure, as much as possible, that the levels of fat, protein, and other nutrients approximate those of breast milk (Table I). A formula, when prepared according to directions, must not require the further addition of any nutritive substance, other than water or a source of carbohydrate, or both.

The Regulations also specify the ratios that must exist between certain nutrients in infant formula, such as those of vitamin E to linoleic acid, calcium to phosphorus, and vitamin B_6 to protein, in order to reflect the interrelationship between these nutrients. Other nutrient substances that are found in human milk may be added to infant formulas (although their addition is not mandatory) provided that the resulting level is the same as that found in human milk.

Food Additives

Only two classes of food additives may be added to infant formulas:

Type I: emulsifying, gelling, stabilizing, and thickening agents;
Type II: pH-adjusting agents, acid-reacting materials, and water-correcting agents.

These are essential to maintain desired consistency and pH levels.

Labels

Formula containers must list the following:

- expiry date of the formula
- adequate directions for the preparation, use and storage after the container has been opened;
- the nutrient value as follows:

a) the content of protein, fat, available carbohydrate, ash, and where present, crude fibre in grams,

b) energy value in calories,

c) vitamins and mineral nutrients in milligrams and International Units,

all expressed both per 100 grams or per 100 millilitres of the formula as sold and in a stated quantity of the formula as normally consumed.

Special Formulas

Provision is made under the Regulations for the sale of infant formulas designed to meet the special dietary needs of certain infants, e.g. low phenylalanine (an amino acid) formulas for infants with phenylketonuria, an inability to metabolize phenylalanine. There are also formulas for

infants who are allergic to milk protein, or who cannot tolerate lactose (milk sugar).

Supplementation

All necessary vitamins are already added to commercial formulas; therefore the formula-fed infant usually does not require vitamin supplements. The formula-fed infant, including the infant fed a formula based on evaporated milk, needs iron supplementation from four months of age. The additional iron should usually be obtained from appropriate food sources such as an iron-fortified infant formula or an iron-enriched infant cereal. Non-food sources of iron should only be used under a doctor's directions.

Precautions in Formula Preparation

It is extremely important to follow manufacturers' directions for formula preparation; too much or too little water can lead to serious effects on an infant's health. Too little water for example can lead to dehydration and even renal failure, because an infant's immature kidneys cannot handle a high concentration of solutes.

It is important to maintain strict cleanliness; bottles, nipples and all containers used in the preparation of formula for infants under the age of four months should be sterilized, and scrupulous cleanliness should be the rule for all infant feedings.

Microwave ovens should not be used to warm formula. Because heating tends to be somewhat uneven, there is a danger of burning an infant with formula that is too hot. In addition, the manufacturers of plastic bottle liners do not recommend the use of their products in microwaves because the plastic may burst or leak.

Baby Bottle Nipples

Rubber baby bottle nipples may contain small amounts of nitrosamines which can migrate into the infant formula or into the saliva. The nitrosamine content of baby bottle nipples sold in Canada is regulated under the Hazardous Products Act and may not exceed 10 parts per billion.

Formula/Cereal Combinations

Certain formula/cereal combinations are now available for infants. Consumers should be aware that these preparations are cereal and they should **never** be used in place of formula, or fed to an infant by bottle. They are essentially "convenience" foods for babies.

Other Milks

Formulas based on evaporated milk may be recommended by some physicians. Such formulas should be prepared according to specific instructions and should only be used when economic resources do not permit the purchase of a commercially prepared infant formula.

Pasteurized whole milk or home-prepared infant formulas based on pasteurized whole milk (either cow's or goat's milk) should **not** be given to infants under six months of age. Milk contains a heat labile factor which has been shown to cause gastrointestinal bleeding in young infants which can lead to anemia. In addition, the protein and the butterfat are poorly digested and the renal solute load and the mineral content are too high and may be harmful for a young infant.

Skim and partly skimmed milks should **not** be given to infants under 12 months of age because their total fat content and energy value (calories) are too low to meet the needs of the infant and their protein and mineral content is too high and can unduly increase the renal solute load.

Sweetened condensed milk is unsuitable for infants because of its high sugar content.

Solid Foods

Breast milk or infant formula is considered to be the only source of nourishment necessary for infants up to four to six months of age. Solid foods may be introduced slowly after that age, one at a time, according to an infant's developmental readiness and as recommended by the health professional. Solids are introduced to provide additional sources of energy and nutrients to an infant's diet. It is very important that only one new food be offered to the infant in small quantities every four to five days to allow for easy detection of food allergies or intolerances. Generally, the recommended sequence of solid food introduction is iron-fortified infant cereals first followed by vegetables, fruits and meats. Large volumes of fruit juices should be avoided as their consumption may jeopardize an infant's intake of other nutrient-rich foods. To avoid the potential for the development of tooth decay, fruit juices should not be fed from a bottle.

Home-prepared Foods

Control of safety and quality in infant foods prepared at home depends on the care taken by the individual who is making the food. Selection, preparation and storage methods as well as cleanliness, are all important considerations.

The advantages of preparing baby foods at home include the fact that home-prepared foods are often less expensive than commercial foods, and the ingredients can be readily controlled. Foods can be prepared without the addition of sugar, salt, starch or additives. Proper cooking methods will ensure maximum nutritive quality.

Guidelines for the Preparation of Homemade Baby Foods

* Overprocessing and loss of nutrients can occur if foods are blended excessively. Operating instructions for blenders should be followed carefully.

* All items used in food preparation should be as clean as possible. This includes the blender, storage containers, strainers and the foods themselves. A good practice is to rinse all utensils in boiling water.

* If infant food is not to be eaten right away, it may be stored in the refrigerator up to three days. Freezing is advisable.

* Canned fruits and vegetables should not be used, at least not exclusively, for infant foods because of the amounts of salt and sugar used in the processing of these foods. In addition, small amounts of lead from the solder used to seal the tins may be found. For this reason, canned fruit juices should be poured into plastic or glass containers once opened.

* **Never** add honey or corn syrup to the food or formula of an infant under one year of age. Spores of *clostridium botulinum* have been found in these sweeteners and can cause infant botulism, a potentially fatal illness.

* Certain foods such as spinach, beets, turnips and carrots contain nitrates which may result in asphyxia in the very young infant. Beets, spinach, turnip and carrots may be offered to infants after six months of age but not on a regular basis. The cooking water should be discarded and the vegetables should be eaten or refrigerated soon after preparation.

Commercial Baby Foods

Commercial baby foods offer a wide variety of products and are convenient, sanitary and processed to retain nutritive quality.

Food Additives

The use of food additives in baby foods is forbidden with the exception of the following:

- ascorbic acid (vitamin C), used in dry cereals containing banana to delay discolouration;
- lecithin, used in rice cereals, to prevent sticking in the manufacturing process and to enhance flavour;
- citric acid, to help maintain colour and flavour by shortening the heating process.

Monosodium Glutamate

Monosodium glutamate (MSG) is classified as a seasoning ingredient. It is no longer added to baby foods.

Modified Starch

Modified starches prepared from wheat, oat, rice and potato flours are added to thicken the product and to maintain its consistency. They contribute carbohydrate, which is used by the body as a source of energy, and negligible amounts of other nutrients.

Salt

By law, salt may not be added to strained varieties of fruit, fruit juice, fruit drink or to cereals. Low levels of salt may be added to other infant foods up to precisely defined limits. The two leading Canadian baby food manufacturers have voluntarily eliminated all added salt from their products.

Sugar

Within the past 10 years, the two leading baby food manufacturers have been reducing or eliminating added sugar in their products.

Labels

The consumer is reminded to read carefully the ingredient list on the label (ingredients are listed in decreasing order of proportion). The composition of baby foods is subject to change, so the wise consumer should check the list each time a product is purchased.

Fluoride

Fluoride in appropriate amounts has been shown to result in a decrease in dental caries by 50 percent. In Canada, most fluoride is obtained from naturally or artificially fluoridated water and this is in fact the preferred way to make fluoride available to children.

Breast milk has a very low content of fluoride which is not affected by the nursing woman's fluoride intake. Infant formulas manufactured in Canada contain very small amounts of fluoride unless they are diluted with fluoridated water.

The Canadian Paediatric Society recommends that in the absence of an adequately fluoridated water supply, all children, beginning within the first 6 months of life, should receive fluoride supplements in a dosage prescribed with consideration of local conditions and in consultation with the dentist or the local dental health authorities.

Other Information on Feeding Infants

For further information on infant feeding, you may wish to refer to the Health and Welfare Canada publication Feeding Babies - A Counselling Guide on Practical Solutions to Common Infant Feeding Questions or contact your provincial or community nutritionist.

Table I: Levels of Fat, Protein and Other Nutrients Required in Formulas

Vitamins, minerals and other nutrients	Minimum amount per 100 available kilocalories		Maximum amount per 100 available kilocalories	
Biotin	2	mcg	-	
Folic acid	4	mcg	-	
Niacin	250	mcg	-	
d-Pantothenic acid	300	mcg	-	
Riboflavin	60	mcg	-	
Thiamine	40	mcg	-	
Alpha-tocopherol	0.6	I.U.	-	
Vitamin A	250	I.U.	500	I.U.
Vitamin B_6	35	mcg	-	
Vitamin B_{12}	0.15	mcg	-	
Vitamin C	8	mg	-	
Vitamin D	40	I.U.	80	I.U.
Vitamin K_1	8	mcg	-	
Calcium	50	mg	-	
Chloride	55	mg	150	mg
Copper	60	mcg	-	
Iodine	5	mcg	-	
Iron	0.15	mg	-	
Magnesium	6	mg	-	
Manganese	5	mcg	-	
Phosphorous	25	mg	-	
Potassium	80	mg	200	mg
Sodium	20	mg	60	mg
Zinc	0.5	mg	-	
Fat	3.3	g	6.0	g
Linoleic acid (in the form of a glyceride)	500	mg	-	
C_{22} Monoenoic fatty acid	-		1	kcal
Protein	1.8	g	4.0	g
Choline	12	mg	-	

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Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"L'alimentation des nourrissons"

Cat. No.: H49-46/11-1990E
ISBN: 0-662-17429-1

Dispatch No. 46

CORRIGENDUM

Dispatch No. 48
Food Additives
What Do you Think?
Highlights of an Opinion Survey
Summer 1979

Dépêche N^{O} 48
Additifs alimentaires
Qu'en pensez-vous?
Points saillants d'une enquête d'opinion menée à l'été de 1979

Page 3, Question 19: should read

19. What is your occupation?

Homemaker	23%
Health professional	7
Other professional/Managerial	21
Clerical/Sales	14
Service/Construction/ Manufacturing	8
Student	17
Pensioned/Retired	4
Other	14

Page 3, question 19: on devrait lire

19. Quel est votre emploi?

Ménagère	23%
Professionnel de la santé	7
Autre catégorie professionnel/ gestionnaire	21
Employé de bureau/vendeur	14
Service/Construction/ Manufacturier	8
Étudiant	17
Retraité	4
Autres	14

Health and Welfare Canada
Santé et Bien-être social Canada

NO 48
DATE Spring 1980

FOOD ADDITIVES

WHAT DO YOU THINK?

highlights of an opinion survey, summer 1979

"Food additives are substances that affect the characteristics of food and do not include salt, sugar, starch, vitamins, mineral nutrients, amino acids, spices, seasonings, flavouring preparations, agricultural chemicals, veterinary drugs, and food packaging materials."
(Food Additive Definition, 1974: Health and Welfare Canada, paraphrased from the Food and Drug Regulations, B.01.001.)

"If it wasn't in the food product to start with or would not have been present naturally but was added at any point in the production of the food, it is a food additive."
(Food Additive Definition, 1979: a Canadian consumer - anonymous, Food Additive Opinion Survey.)

In the summer of 1979 Educational Services of the Health Protection Branch (HPB) planned and implemented a cross-Canada consumer opinion survey on food additives. Canadians were asked such questions as

What is a food additive?
Is the control of food additive use adequate?
What foods contain additives?
Is the public assured that long-term ingestion of additives is safe?

The objectives of this survey were to assess consumer knowledge of food additives in order to plan more effective educational programs and to provide a means for the consumer to communicate opinions on control, use, and health effects of food additives.

CONDUCTING THE SURVEY

The survey took place over an 8-week period, June 25 to August 18, 1979.

A voluntary, anonymous, self-administered questionnaire in the official language of choice was administered from booths set up in five urban centres across Canada: Vancouver, Winnipeg, Toronto, Montreal, and Halifax. Mail-in cards requesting food additive information were also handed out. The surveyors were 20 college/university students sponsored by the Youth Job Corps and organized into five teams (one team per city). The survey sample was adult Canadians (16 years plus) who frequented the shopping centres where the booths were set up. Shopping centres with supermarkets were usually chosen as the survey locations. With two exceptions, each mall was surveyed for 1 week, for a total of at least eight survey locations per city. A geographic cross-section of mall locations was achieved within the greater city limits of the five urban regions.

Educational Services, Health Protection Branch

dispatch

COMPILING THE DATA

Questionnaires containing written comments were tabulated by Educational Services. All questionnaires were forwarded to the Field Operations Directorate, HPB, for computer processing by the Systems and Operational Planning Division.

HIGHLIGHTS OF FINDINGS

A total of 24 940 people filled out the questionnaire in the five cities, with a percentage breakdown as follows: Vancouver, 35%; Winnipeg, 16%; Toronto, 27%; Montreal, 11%; and Halifax, 11%. The male-female ratio was 36%:63% (approximately 1:2).

More than 20% of the respondents (5224) took the time to make additional comments and about 14% (3443+) sent in the provided mail-in card requesting information on additives.

General trends within the sample have been identified and are outlined below. (See also the questionnaire with majority response indicated in percent.)

REGULATIONS (STATEMENT 1): Canadian government regulations limiting the use of food additives by manufacturers do exist, with present legislation dating back to 1964. At that time, lists of permitted additives were established after careful review of all data available on the acceptability of each compound. Provision has always existed under the Food and Drugs Act to prohibit the use of any substance considered harmful for use in foods. The majority of those sampled (61%) knew that there were such Canadian government regulations; however, 26% was unsure. More positive responses were recorded from those in the higher education levels and more of the males. The 16-25 age-group was less sure of the existence of additive legislation. The comments on this statement (138) revealed concern about inadequate regulations and the desire for more government enforcement.

LABELLING (STATEMENT 2): Food products must carry a list of ingredients, including additives, in descending order of proportion or as a percentage of the prepackaged product. For the most part, those surveyed indicated dissatisfaction with labelling information on food additives. The response was fairly uniform for all subsamples according to sex, age, shopping responsibilities, occupation, and level of education. More respondents in Quebec (43%) felt there was adequate label information than the other regions (33, 34, 35, and 31%). The subject of labelling received the most attention from comment writers (533). There was disbelief that all ingredients and additives are listed on the label; suggestion that names of specific flavours and colours be given; some difficulty in understanding chemical names; and a request for additive warnings on labels.

SAFETY TESTS (STATEMENT 3): Food manufacturers who want to use a new additive must carry out safety tests and submit the results to the Health Protection Branch for evaluation. Many of the respondents (57%) knew manufacturers must test all new additives before their use in food. A great number (26%) were unsure. Surveyees in Ontario and Quebec were more positive than those from the east and west coasts. The 16-25 age-group was more assured about safety testing that the older groups. College/university educated respondents and those principally in charge of household shopping were less positive. There were 156 comments on safety testing. Several indicated a mistrust of food manufacturers to conduct unbiased tests and concern about lack of long-term safety tests and about cumulative effects of food additive ingestion. Some suggested that safety testing be the responsibility of independent laboratories.

CONTROL (STATEMENT 4): 68% of the respondents did not feel that adequate control of food additives exists. Greater concern was expressed by females, principal shoppers, and those with higher education. The 16-25 age-group and those from Quebec were less concerned. Written comments totalled 205 on the additive control subject. Some expressed concern over manufacturers' influence on government decisions.

FOOD QUALITY (STATEMENT 5): According to 70% of the sample, food additives do not improve the quality of food. Quebec respondents were not quite as adamant. Females, principal shoppers, and those with higher education levels tended to doubt the need for additives in improving the quality of food more than did their counterparts. Comments on this subject totalled 98 and mainly expressed concern for the generality of the statement. Those who commented

MAJORITY RESPONSE TO FOOD ADDITIVE OPINION SURVEY (% INDICATED)

INDICATE WHETHER YOU AGREE OR DISAGREE WITH EACH STATEMENT MADE BELOW ABOUT FOOD ADDITIVES BY CHECKING (✓) THE APPROPRIATE BOX.

1. There are Canadian Government regulations limiting the use of food additives by manufacturers.

   (Yes) 61% No 12% Unsure 26%

2. I can find all additives used in a food listed on the label.

   Yes 34% (No) 50% Unsure 15%

3. Manufacturers must carry out safety tests on all new additives before they can be used in food.

   (Yes) 57% No 17% Unsure 26%

INDICATE THE DEGREE TO WHICH YOU AGREE OR DISAGREE WITH EACH STATEMENT MADE BELOW BY CIRCLING THE MARK ON THE SCALE____.

4. I feel there is adequate control of food additives.

2%	13	17	41	27%
strongly agree	agree	unsure	(disagree)	strongly disagree

5. Food additives improve the quality of food.

2%	14	14	40	30%
strongly agree	agree	unsure	(disagree)	strongly disagree

6. The addition of colours to food is justifiable.

2%	17	11	37	32%
strongly agree	agree	unsure	(disagree)	strongly disagree

7. I am prepared to pay more money for food if it is additive-free.

22%	38	13	19	8%
strongly agree	(agree)	unsure	disagree	strongly disagree

8. I make an effort to eat food with less additives.

34%	42	9	13	2%
strongly agree	(agree)	unsure	disagree	strongly disagree

9. I am concerned about the possible effects of food additives on my health.

49%	38	7	5	1%
(strongly agree)	agree	unsure	disagree	strongly disagree

10. I need more information about food additives.

47%	44	4	3	1%
(strongly agree)	agree	unsure	disagree	strongly disagree

COMPLETE THE FOLLOWING:

11. My greatest concern about the safety of the food supply is the presence of:

	CHECK ONE
Pesticides	30%
Bacteria	30
(Food Additives)	35
Pollution from Industry	16
Other _____ Please indicate	8

CHECK (✓) WHETHER YOU CONSIDER EACH ITEM TO BE A FOOD ADDITIVE:

12.	Yes	No	Unsure
Salt	41%		
(Emulsifiers)	54		
(Flavour Enhancers (MSG))	85		
(Pesticides)	52		
Vitamins	44		
(Food Colouring)	88		
(Sugar)	55		
(Preservatives)	80		

CHECK (✓) WHETHER EACH FOOD CONTAINS ADDITIVES:

13.	Yes	No	Unsure
(Fresh Meat)	52%		
(Soda Crackers)	72		
Frozen Peas	48		
(Fluid 2% Milk)	56		
(Processed Cheese)	79		
(Canned Orange Juice)	64		

PLEASE VOLUNTEER SOME INFORMATION ABOUT YOURSELF.

14. male 36%
    female 63

15. Are you the principal shopper in your household? Yes 65% No 34

16. Province you are in today.

British Columbia	35%
Manitoba	16
Ontario	27
Quebec	11
Nova Scotia	11

17. Age (years)

16 - 25	33%
25 - 35	32
36 - 45	15
Over 45	19

18. Education

Elementary	5%
High School	47
College/ University	47

19. What is your occupation?

Homemaker	16%
Health professional	6
Other professional/Managerial	12
Clerical/Sales	24
Service/Construction/ Manufacturing	9
Student	12
Pensioned/Retired	14
Other _____ Please indicate	6

20. Sources where you have obtained information about food additives:

School	30%
Doctor/Nurse	15
Nutritionist/Dietitian	20
Magazine/Newspapers	67
Government Pamphlets	24
Health Food Store	24
T.V./Radio	46
No Source	7
Other _____ Please indicate	14

* Circling indicates majority response.

were selective in their choice of what additives they thought were necessary. For example, many recognized the need for food preservatives, but considered food colours unnecessary additions.

COLOURS (STATEMENT 6): 69% did not agree that food colours were a justifiable addition to food, with more disagreement registered in greater numbers by females, principal shoppers, and those with post-secondary education. The 16-25 age-group and those from Quebec were less likely to doubt the necessity of using food colours. Comments totalled 111 on this issue; many emphasized their disagreement with the use of colours in food.

HEALTH EFFECTS AND PERSONAL CHOICES (STATEMENTS 7, 8, AND 9) : 87% of the respondents were concerned about the possible health effects of eating additives. The 16-25 age-group and those from Quebec were not as worried as the others, and principal shoppers and females were the most concerned. Comments on statement 7 totalled 316. Some related allergic reactions and cancer to food additive intake. Others felt that eating additives had a negative influence on their general physical well-being.

Sixty percent (60%) want additive-free food enough to say they are willing to pay more for it; however, many of the 276 who also commented on the subject felt it was illogical to pay more for less (no additives). The 16-25 age-group appeared less willing to pay more for additive-free food.

Seventy-six percent (76%) said they made an effort to eat food containing less additives. Of the 173 who made comments, many felt this would be easier if there were a better selection of additive-free food. The 16-25 age-group once again differed, making less of an effort to eat additive-free food than the others.

INFORMATION (STATEMENTS 10 AND 20): A desire was expressed by most respondents (91%, statement 10) for more information on food additives; 497 written comments reemphasized this need. Most people, in the past, obtained their additive information from print and radio/television media (statement 20). Health professionals were low on the list as sources of additive information.

SAFETY OF THE FOOD SUPPLY (STATEMENT 11): Food additives were selected by the overall survey sample as the greatest safety concern for the food supply. Following in descending order of concern were pesticides and bacteria (equally rated), industrial pollutants, and "other". The "other" category covered many individual suggestions, a large proportion of which were people who thought all four considerations were equally important. The greatest concern of the non-principal shoppers and those in the 16-25 age-group was bacteria.

ADDITIVE CLASSES (STATEMENT 12): The list of additives permitted for use in foods by the Food and Drug Regulations is organized into 15 tables (according to function), with categories such as colouring agents, bleaching, maturing, and dough-conditioning agents, preservatives, and pH-adjusting agents. Sugar and salt are considered ingredients and therefore are not food additives; neither are vitamins and minerals, spices, seasonings, flavouring preparations, pesticides, and drugs administered to animals that may be consumed as food. The survey sample correctly chose emulsifiers, food colours, and preservatives as food additives. In addition, flavour enhancers (e.g., MSG), pesticides, and sugar were also thought (incorrectly) to be food additives. The choices of the Quebec sample were closest to those defined by federal regulations to be additives. The 78 comments on this subject showed that the legal food additive definition is not known.

FOODS WITH ADDITIVES (STATEMENT 13): Additives were considered virtually ubiquitous in food. Frozen peas was the only food of the six listed not felt by the majority (correctly) to contain food additives. Even at that, 48% thought there were additives in the peas. Of the six items, federal regulations permit additive use in three: soda crackers, processed cheese, and canned orange juice. Fresh meat, frozen peas, and partially skimmed (2%) milk do not contain additives. The 44 comments indicated a belief that foods do not need to contain additives and showed that again the food additive definition is variable.

CROSS-TABULATIONS: Four cross-tabulations were carried out; i.e., the results of one statement were related to those of another. The tabulations were done for the general response ter

the statement and for all the variables, e.g., principal shopper, male, female, province, etc. The results for the general response and for any outstanding variable are outlined below.

Statements 1 x 4 - 83% of the survey sample who knew that government regulations limiting additive use exist did not feel present controls are adequate. In Quebec, those who knew about federal legislation were less likely to feel it is inadequate.

Statements 3 x 9 - 56% of the survey sample were concerned about food additives and knew that safety tests must be carried out; 44% were concerned about the health effects but were unsure or disagree that the safety tests exist. The higher education groups who were concerned about food additives were less aware or less sure that all new additives are tested.

Statements 8 x 9 - 84% of the respondents who were concerned about the health effects of food additives were also trying to limit their additive intake; 78% of the principal shoppers were making an effort to eat less additives. Only 58% of those not responsible for household shopping were concerned about additives and were trying to limit their intake.

Statements 8 x 13 - All six foods were identified as containing additives by those attempting to limit their additive intake; 85% of the principal shoppers were trying to limit additive intake but believed all six items contain additives.

SOME INTERESTING COMMENTS: Over 5000 surveyees took the opportunity to write comments on the appropriate section of the questionnaire. These comments have added zest and colour to the survey results as well as providing valuable information. Some are reproduced verbatim below and show the diversity of opinion on food additives.

Necessity of additives:

> Some additives are necessary. Bacteria-free food is better than additive-free food.
>
> Although some preservatives may be required for a long shelf life, I would prefer to change my shopping habits and extend my shelf life.

Government responsibility:

> Vous, les autorités, agissez au plus tôt avant que le genre humain disparaisse par empoisonnement.
>
> I have absolutely no confidence in government at any level controlling the use of food additives.

Manufacturers:

> I have great confidence in our private industry to provide us with high quality and cheap foods.
>
> If you can prevent lobbying and pressure from food corporations on provincial and federal governments you might begin to improve the quality of the food we eat.

The survey:

> You say our response will be used to plan consumer programs. Why programs? Why not go direct to the processors? You are bypassing the problem.
>
> Bravo pour cette initiative!

CONCLUSIONS

Many areas of confusion and concern have been identified from the responses of 25 000 Canadians to the Food Additive Opinion Survey.

There was a difference between what the government considers a food additive and what the general public perceived an additive to be. This misunderstanding must be resolved in the interest of coherent discussion.

Although government regulations and safety testing of additives were known to exist, control of additive use was not considered adequate by many respondents.

Addition of colours to food was not considered to be justifiable by many respondents.

Labelling of additives was thought to be inadequate by many respondents. Does this mean that consumers want more specific labelling of additives or that they are not well-informed on how to effectively use these labels?

The majority of respondents were concerned about the effects of food additives on their health. They were making an effort to eat less additives, yet most were unaware what a food additive is (by legal definition) or what foods contain additives.

People expressed a need for more information on food additives. In the past, this type of information has been obtained mainly from magazines/newspapers and television/radio. Health professionals are not being used as a major source of food additive information.

Where do we go from here? Health Protection Branch is communicating the results of the survey to food manufacturers, health professionals, and consumers. Resolving consumer concerns and confusion on the subject of food additives can come about only through the cooperation of these groups.

REFERENCE

Health and Welfare Canada, Health Protection Branch. 1980. Report on Food Additive Opinion Survey Conducted Summer 1979. Prepared by Educational Services (limited availability).

Dispatch No. 49

The Addition of Nutrients to Food

Over the past decade or so, notable changes have occurred in Canadian food habits and in the nature of the available food supply. People now buy an increasing variety of partially prepared, processed and substitute foods. These changes, coupled with knowledge of the population's nutritional status and improved methods of food technology, have been important factors influencing current regulations concerning the addition of nutrients to food.

Rationale Guiding Addition of Nutrients to Foods

The Health Protection Branch, which develops nutritional standards and guidelines for food enrichment programs, issued *Guidelines for the Addition of Nutrients to Foods* in 1971. The conditions under which nutrients may be added to foods include the following:

- To correct a demonstrated deficiency of a nutrient in the Canadian diet or in a specific population group.
- To restore nutrients lost in the course of good manufacturing practice provided these were present in significant amounts prior to processing.
- To ensure the nutritional quality of foods sold as substitutes for traditional foods.
- To ensure the nutritional quality of products used as the sole source of nourishment.

Correction of a Demonstrated Deficiency

A successful food fortification program should take the following principles into consideration:

- It must be demonstrated that a significant number of people consume less than desirable intakes of the added nutrient.
- A food chosen to supply a nutrient should be eaten in quantities which will make a significant contribution to the diet of the population in need.
- Addition of the nutrient should not create a dietary imbalance.
- The levels of fortification must not be so high as to cause excessive nutrient intakes.

Vitamin D addition to milk serves as a good example of a nutrient added to a food to correct a demonstrated deficiency. Because of insufficient vitamin D in the Canadian diet, Canadians used to depend on a supplement such as fish liver oil as their source of this vitamin. Milk was then chosen as a vehicle for vitamin D fortification because it is a food readily available and commonly consumed by the segment of population with the greatest need for this nutrient - infants, children and pregnant and lactating women. Furthermore, milk contains naturally high levels of calcium and phosphorus, which are absorbed and metabolized under the influence of vitamin D.

An example of fortification serving a more select segment of the population is the addition of vitamin C to canned milk. Originally added to prevent scurvy in infants fed infant formula made from canned milk, vitamin C now also serves a similar function for people living in remote areas. Vitamin C deficiency is possible among these isolated populations because of limited access to supplies of fruits and vegetables. Since canned milk is not widely consumed by the remainder of the Canadian population, its vitamin C content primarily reaches the target group needing it. Similarly, the Food and Drug Regulations permit the addition of calcium to flour to provide this nutrient to people living in areas where milk products are not consumed in appreciable quantities because of cultural reasons or lack of availability. This practice is mandatory only in Newfoundland, although populations of isolated northern regions may lack a dietary source of calcium if dairy products are not readily available.

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Restoration of Nutrients Lost in Processing

Only specified foods are required or permitted to have nutrients restored to the same levels as existed prior to processing. Whether or not a nutrient is sufficiently significant to merit restoration depends on the level of the nutrient in the unprocessed food and the importance of the food as a dietary source of that nutrient.

The classic example of restoration is the enrichment of flour. Whole-grain products are significant dietary sources of thiamine, riboflavin, niacin, vitamin B_6, folic acid, pantothenic acid, iron, magnesium, copper, zinc, phosphorus and fibre. Unenriched white flour contains significantly lower levels of these nutrients and fibre due to the removal of the bran and the germ. The enrichment of flour with thiamine, riboflavin, niacin and iron was optional until 1976, when the Food and Drug Regulations were amended to make mandatory the addition of thiamine, riboflavin, niacin and iron and to permit the optional addition of vitamin B_6, folic acid, pantothenic acid and magnesium to white flour.

Table I presents the list of traditional foods to which nutrients are added in order to correct a demonstrated deficiency or to restore nutrients to preprocessing levels.

Addition of Nutrients to Substitute Foods

It is the policy of the Health Protection Branch that substitute foods should not be nutritionally inferior to the foods they replace. Underlying this policy are two basic assumptions. First, people can be well nourished when eating foods from the four food groups described in *Canada's Food Guide*. Second, the distribution and levels of nutrients found in a selection of foods as recommended by *Canada's Food Guide* are safe and do not result in imbalanced or excessive intakes. If substitute foods are to be used in the same manner as the foods they replace, it follows that their nutrient content should be equivalent. However, *absolute* nutritional equivalency is usually not possible because of technical problems or insufficient knowledge.

Addition of Nutrients to Foods Used as Sole Source of Nourishment

Infant formulas, formulated liquid diets and meal replacements are examples of foods which may be used as the sole source of nourishment. Meal replacements are single, formulated foods, which can be used in place of a meal or in weight reduction diets as the sole source of nutrients. The guidelines of 1971 stated that meal replacements should contain essential nutrients including energy in amounts related to the purpose of the described meal. (Levels of nutrients in meal replacements are based on the recommended intakes set out in the *Recommended Nutrient Intakes for Canadians*.)

Regulations were promulgated in 1978 to control the levels of protein, fat, carbohydrates, vitamins and minerals in these products.

- Protein content must provide not less than 20% and not more than 40% of energy.
- Fat content is limited to 35% of energy.
- Sugar may account for not more than 30% of the available carbohydrates (except for liquid meal replacements and cookies or biscuits without any filling or icing).
- A serving of the food when ready to serve must contain at least 225 kilocalories (1 MJ, where MJ = megajoule). If the product is sold or advertised as a replacement for all meals in a diet, it must provide a daily energy intake of at least 900 kilocalories (4 MJ).
- Each serving of the food must contain a prescribed list of vitamins and minerals, each of which must be present within a specified minimum and maximum range.

Table II presents a list of substitute and formulated foods for which nutritional standards have been developed.

Selection of Nutrients for Addition to Foods

The following factors are considered by manufacturers when selecting a nutrient for addition to foods and by the Health Protection Branch when developing regulations:

- The added nutrient should be stable in the food during the process of manufacture.
- The added nutrient should be stable under normal conditions of use. Therefore, packaging and storage conditions must be considered.
- The nutrient should be physiologically available.
- The added nutrient should not significantly alter the colour, taste, or form of the food. In cases where the Health Protection Branch recognizes technical problems in adding certain nutrients to foods, the regulations are designed to take these into account.

Table I. Traditional Foods to Which Nutrients Are Added

Foods	Nutrients that *must* be added	Nutrients that *may* be added
Alimentary pastes (pasta)	-	Thiamine, riboflavin, niacin, iron
Breakfast cereals	-	Thiamine, niacin, folic acid, vitamin B_6, pantothenic acid, magnesium and iron
Infant cereal products	-	Thiamine, riboflavin, niacin, calcium phosphorus, iron, iodine
Flour, white flour, or enriched white flour (Bread, enriched*)	Thiamine, riboflavin, niacin, iron	Vitamin B_6, folic acid, pantothenic acid, magnesium, calcium
Juices	-	Vitamin C
Milk, all forms including flavoured milks	Vitamin D	-
In addition:		
Skimmed and partly skimmed (fresh, canned, powdered, flavoured)	Vitamin A	-
Canned evaporated	Vitamin C	-
Goat's milk and goat's milk powder	-	Vitamin D
Skimmed and partly skimmed goat's milk and goat's milk powder	-	Vitamins A and D
Evaporated goat's milk, evaporated partly skimmed and skimmed goat's milk	-	Vitamins A, C and D, folic acid
Potatoes, dehydrated	-	Vitamin C
Pre-cooked rice	-	Thiamine, niacin, folic acid, vitamin B_6, pantothenic acid, iron
Salt for table use	Iodine	-

* Nutrients come from the enriched flour that must be used in the making of enriched bread.

Table II. Substitute and Formulated Foods for Which Nutritional Standards Have Been Developed

Foods	Vitamin and mineral nutrients
Breakfast replacement foods, ready breakfast, instant breakfast	Vitamins A and C, thiamine, niacin, riboflavin Iron
Egg, simulated whole	Vitamin A, thiamine, riboflavin, niacin, pantothenic acid, vitamin B_6, vitamin B_{12}, folic acid, vitamin E Calcium, iron, zinc, potassium
Fruit-flavoured drinks and bases, concentrates and mixes sold as a substitute for fruit juice or as a breakfast drink	Vitamin C; folic acid and thiamine are optional Iron and potassium are optional
Infant formulas	Vitamins A, C, D, E, K, B_6, B_{12}, folic acid, thiamine, riboflavin, niacin, biotin, pantothenic acid Calcium, chloride, copper, iodine, iron, magnesium, manganese, phosphorus, potassium, sodium, zinc
Liquid diets, formulated	Vitamins A, C, D, E, B_6, B_{12}, folic acid, thiamine, riboflavin, niacin, pantothenic acid; vitamin K* and biotin* are optional Calcium, copper, iodine, iron, magnesium, phosphorus, zinc, sodium, potassium; manganese* and chloride* are optional
Margarine and other similar substitutes for butter	Vitamins A and D; E is optional
Meal replacements including those represented for use in a weight reduction diet	Vitamins A, C, D, E, B_6, B_{12}, folic acid, thiamine, riboflavin, niacin, biotin, pantothenic acid Calcium, copper, iodine, iron, magnesium, manganese, phosphorus, potassium, sodium, zinc; chloride* is optional
Simulated meat and poultry products, meat or poultry product extenders	Thiamine, riboflavin, niacin, pyridoxine, pantothenic acid, folic acid, vitamin B_{12} Iron, magnesium, potassium, zinc, copper

N.B.: The Food and Drug Regulations set minimum levels of vitamins and minerals which must be present in the above foods. In some cases, ingredients may contain sufficient amounts of naturally occurring nutrients so that their addition is not necessary.

* For the optional nutrients marked with an asterisk, minimum levels have not been set because of insufficient data at the time when the product regulations were written.

Nutrient Stability in Enriched Foods

Proper storage and preparation methods to retain nutrient content are as important for enriched and fortified foods as for traditional foodstuffs. Manufacturers add more than the required levels of nutrients that are less stable to ensure that food products will meet label declarations at the time of sale. In the home or institution, cool storage will enhance retention of heat-sensitive nutrients such as thiamine in cereal products and vitamin C in fruit juices and drinks, canned milk, infant formula, etc. Foods stored in a warm cupboard over a stove, in a closet, or in the sun can lose significant amounts of vitamins within a short time. Similar deterioration will occur with repeated thawing and refreezing. Preparation methods emphasizing fast cooking time in minimal water reduce losses of added as well as naturally occurring nutrients.

Making a Choice

With the growing selection of new food products being made available every year through modern technology, and with this technology affecting the foods we have long considered "traditional," the consumer is confronted daily with numerous choices when shopping for food. By assessing the comparative values of convenience, cost and nutrient composition, the individual can make an informed decision.

If the nutrient content of an enriched or substitute food product is in question, the food label can often be turned to for helpful information. Additional information is available from food composition tables such as the *Canadian Nutrient Value of Some Common Foods*. When American references are used, care should be taken that appropriate adjustments are made for the different regulatory requirements that apply to Canadian and American food supplies. If neither of the previous sources provides the required information, then the manufacturer can be directly contacted.

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Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"L'addition d'éléments nutritifs aux produits alimentaires"

Cat. No.: H49-46/10-1990E
ISBN: 0-662-17428-3

Dispatch No. 50

Food and Drug Interactions

Milk and tetracycline -- the former is a food, the latter a drug. When taken together, they constitute a food and drug interaction Such interactions are often complex and sometimes subtle. They may be manifested in two ways.

- Certain foods or patterns of dietary consumption alter drug absorption, effectiveness, or metabolism.
- Some drugs are capable of impairing or altering the absorption and utilization of nutrients.

Alteration of Drug Action by Nutrients

Many factors can affect the speed at which a drug is absorbed into the blood and transferred to the site where it is needed -- patient size, age and medical condition, dosage of drug and the presence of food in the digestive tract. Natural or added chemicals that make up food can also react with drugs in certain ways that inhibit or change their effectiveness. Some food-drug interactions can be dangerous to the point of being life-threatening.

Dairy Products and Antibiotics: Certain antibiotics (notably the tetracyclines) lose their effectiveness when taken with dairy products. The absorption of tetracycline is delayed when it binds with the calcium in milk or milk products (e.g. yogurt, cheese, etc.) and forms an insoluble complex. Antacids, which usually contain aluminum, calcium or magnesium, also bind in the same way with tetracycline. The adverse interaction results in a delay rather than a complete failure of the drug to be effective. However, such a delay can be critical when treating a disease.

Cheese, Herring, Wine and MAO Inhibitors: One of the most serious of food and drug interactions is that of the activity of certain naturally occurring amines called pressor amines (e.g. tyramine) with antidepressant drugs that inhibit the activity of monoamine oxidase (MAO). These amines, which can cause vasoconstriction and ultimately high blood pressure, are normally detoxified by high concentrations of monoamine oxidase present in the gastrointestinal tract and liver. If patients receiving MAO inhibitors eat foods high in pressor amines, they can experience severe headaches, dizziness, and in some cases, cerebral hemorrhaging, all symptoms of a high rise in blood pressure. Some deaths have occurred from this interaction. Foods high in tyramine, the most common pressor amine, are aged cheeses, chicken liver, pickled and smoked herring, canned figs, pineapples, broad beans, and some dry red wines. Patients receiving MAO inhibitor drugs must be counselled to avoid such foods.

Foods and Acid-Labile Antibiotics: Erythromycin, ampicillin and penicillin G are partially destroyed by excess stomach acid. For this reason, instructions for use entail taking on an empty stomach and not at the same time as acid beverages.

Alcohol and Drugs: Although perceived by many to be a drug, alcohol is classified as a food under the Food and Drug Regulations. It makes up a significant part of the diet of many Canadians. Alcohol has been shown to increase the sedative properties of many antihistamines (most of which are available as over-the-counter remedies), barbiturates, sedatives, certain analgesics such as propoxyphene, and some other drugs. The effects of alcohol on oral anti-coagulants such as warfarin and phenindione are unpredictable: in some cases, drug action may be inhibited and in others, it may be enhanced. Patients on oral anticoagulants should restrict their alcohol intake. Alcohol and nitroglycerin can cause severe hypotension. In patients taking metronidazole, alcohol can cause an Antabuse-like reaction.

Deaths have occurred from alcohol-drug interactions and it is a wise policy not to mix the two, unless a physician or pharmacist has been consulted and advised that no problem exists.

Xanthines and Drugs: Large doses of xanthines, found in coffee, tea and maté, may decrease the activity of uricosuric drugs (used for treating gout) as well as the activity of oral anticoagulants.

Licorice and Drugs: Very high intakes of licorice have been reported to have caused elevation of blood pressure and loss of potassium. The effects of antihypertensive drugs could be counteracted, digitalis-like drugs could become more toxic and severe loss of potassium could occur in patients taking thiazide diuretics.

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Vitamin B_6 and Levodopa: Levodopa and its derivatives are used in the treatment of Parkinson's disease. A daily dose of as little as 5 mg of Vitamin B_6 (pyridoxine) has caused a reversal of the effect of the drug. However, Vitamin B_6 in a normal diet (about 2 mg/day) should not affect the drug.

Drug-Induced Nutrient Deficiency

Many drugs impair the absorption and use of nutrients and electrolytes. Deficiencies occur more often with drugs taken for long-term treatment or when the disease state predisposes a patient to a deficiency.

Potassium and Anti-Hypertension Drugs: Diuretics are often used in combination with other drugs for patients with high blood pressure. Such drugs (e.g. chlorothiazide, hydrochlorothiazide, quinethazone, chlorthalidone), which help excrete sodium, are also capable of depleting potassium. This is especially serious in the case of heart patients being treated with digitalis which also lowers potassium. With a lack of potassium, the heart may become more sensitive to the toxic effects of digitalis. General muscle weakness is the usual symptom of low potassium.

Potassium depletion can be corrected by changing the diet to include foods high in potassium or, in some cases, by taking supplements of potassium chloride. Some foods high in potassium are nuts, citrus juices, dry fruits, bananas, molasses, bran, wheat germ, watermelon and tomato juice. Note that salted nuts and most brands of tomato juice or similar preparations contain significant amounts of sodium.

Folic Acid, Vitamin B_6 and Oral Contraceptives: Some women using oral contraceptives have displayed symptoms of folic acid and vitamin B_6 deficiencies. The reasons for these deficiencies have not yet been clearly established. Women on The Pill should eat nutritionally balanced meals and discuss the need for vitamin supplementation with their physician.

Folic Acid, Vitamin B_{12} and Anticonvulsants: People with epilepsy on long-term treatment with some anticonvulsant drugs such as diphenylhydantoin, are susceptible to megaloblastic anemia. These drugs decrease levels of folic acid and vitamin B_{12} by speeding up their metabolism. Supplements should be given to all patients at the time anticonvulsant therapy is started.

Vitamins A, D, E, K and Mineral Oil: Chronic and excessive use of mineral oil laxatives can result in deficiencies of carotenes, and the fat-soluble vitamins A, D, E and K. The mineral oil interferes with the absorption of these nutrients by the gut. Many laxatives are available as over-the-counter remedies and are used for self-treatment. A person is cautioned against long-term use of such drugs; in the case of persistent constipation, it is always wise to check with a doctor.

Medication and Nutrition: A Shared Responsibility

Adverse food and drug interactions are not easy to predict or detect. Much research still has to be done in the area. Cooperation among the health professionals involved -- doctor, nurse, pharmacist and nutritionist -- is essential for patient safety. The patient must share in the responsibility for safe and effective drug use by reading labels and patient package inserts, following the doctor's order on drug taking, and maintaining a well-balanced diet.

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Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"Les interactions aliment-médicament"

Cat. No. H49-46/6-1990E
ISBN 0-662-17424-0

Dispatch No. 51

Control of Pesticide Residues in Food

In the last 35 years, pesticides have become an important factor in food production. With increased use of these agricultural chemicals, however, many people have become concerned about the effect of pesticides on their health and the environment. The Health Protection Branch of Health and Welfare Canada, under authority of the Food and Drugs Act, is charged with the responsibility of ensuring that foods offered for sale to Canadians are fit for consumption in that they are safe, clean and unadulterated. In this capacity, the Branch determines the nature and quantity of pesticide residues that may remain on crops at time of harvest or in animals at time of use for food (i.e. meat, eggs, milk, etc.) and that are considered safe for human consumption. There are provisions in Division 15 of the Food and Drug Regulations to list pesticides and their maximum residue limits for particular food products.

Other government departments are involved in regulating the use of agricultural chemicals. The federal Department of Agriculture reviews and registers products under the authority of the Pest Control Products Act. This department deals with the efficacy of the product, directions for use, the crops or products on which it can be applied, and adverse effects on the environment. Provincially, the departments of agriculture advise farmers regarding application and spraying programs, and the departments of health or environment regulate or assist in the control, distribution and handling of pesticides.

Evaluation of Submissions

The Health Protection Branch requires manufacturers of pesticides for which maximum residue limits on foods are to be established to submit detailed data on the following:

- specifications and composition of the substance to be used as a pesticide;
- the physical and chemical properties of the substance;
- plant and animal metabolism studies;
- evidence that the product is effective and practical;
- the amount to be applied, frequency and time of application;
- satisfactory method of analysis for determining residues in foods;
- studies designed to determine residue levels on each food;
- toxicity studies; and
- a proposed maximum residue limit for each food.

The manufacturer may need to do 5-10 years of work in order to develop sufficient information to demonstrate the value and safety of a new product.

Toxicity studies: The manufacturer is normally required to carry out several types of toxicity studies, for example, acute, subacute and long-term. The studies take into account such factors as sex, dermal exposure, inhalation exposure and oral ingestion.

Acute studies are single dose LD50 experiments. An LD50 is the dose that is lethal to 50 percent of the population of experimental animals.

Subacute studies are short-term feeding experiments; they are designed to find out effect and no-effect levels from a range of low dosages and to further investigate the range of effects caused by the chemical. They also give an indication of the levels to use in the long-term studies, thus avoiding needless expenditure of time and money.

The long-term or chronic studies normally involve two species of animals and last approximately two years; various dosage rates are used. In addition, studies, such as those on reproduction and teratogenicity, are usually conducted. Upon completion, various organs including the liver, the heart and the kidneys are examined grossly and microscopically by trained pathologists.

Determining the Acceptable Daily Intake: From both the manufacturer's toxicity studies and other data which may be available, the Branch determines the dose per unit of body weight producing no observable adverse effect in

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animals. The lowest "no-effect dose" from any of the toxicity studies is then divided by a safety factor, usually 100, but it can range between 10 and 5000 depending on the pesticide; the figure thus obtained is regarded as an acceptable daily intake (ADI) for humans of that particular pesticide. The ADI is the amount of pesticide that toxicologists consider to be safe for humans to consume each day for an entire lifetime. In general, these levels are in close agreement with the ADIs recommended by the World Health Organization (WHO).

Setting Maximum Residue Limits: Maximum residue limits for pesticides on food are established by determining the amounts likely to remain in food at point of sale (e.g. harvest of crops, slaughter of animals) after pesticides are used in accordance with registered uses or good agricultural practice. Such residue limits are only accepted providing that the total consumption of residues from all food uses will not exceed the ADI for the particular pesticide.

The permitted level of pesticide residues varies from no detectable residues to several parts per million, depending on the use patterns and the pesticide concerned. Residues in excess of legal limits are in violation of the Food and Drugs Act and Regulations.

Approximately 250-300 pesticide chemicals are registered in Canada for use in the production or handling of various foods. Health Protection Branch has established residue limits for about 100 of these. The remaining chemicals include those too toxic for any of their residues to be allowed to remain on foods, those not likely to leave any residue because of their chemical nature or the way they are applied, and those exempt from the requirement to set residue limits because of their low toxicity.

Enforcement

The Health Protection Branch's Field Operations Directorate is responsible for investigating possible violations of accepted residue levels. This program includes monitoring, inspection, education and involves the analysis for pesticide residues of some 2000 samples of imported and domestic foods each year.

When excessive residues are found in food, a thorough investigation is conducted to determine their source and extent. When the information indicates a violation of the Food and Drugs Act and Regulations, appropriate action is initiated and may involve removal of foods from the food outlets, seizure of food stocks, rejection of imports, or prosecution.

Food inspectors of Health and Welfare Canada maintain close liaison with local agriculture officials and other agencies and participate in education programs carried out to inform the users of pesticides about permitted residue limits in food and potential hazards associated with misuse of these chemicals.

Imported foods: Approximately 50 percent of the food samples taken for pesticide analysis are imported foods. Such foods are often treated not only during growing, but also during storage and shipment. An example is citrus fruit, which must be protected from rots and moulds with fungicides; otherwise, transportation of such food products would be nearly impossible. Such pesticides are often listed on the labels of the food containers by the exporting country.

Only those pesticides evaluated by the Branch and considered acceptable are permitted on foods imported into Canada.

Research

In the laboratories of the Health Protection Branch, research is conducted to find more sensitive methods of analysis and to learn more about residues and their long-term effects. The "total diet" concept has also been used over the last 10 years to estimate the pesticide residue intake of urban Canadians from food prepared for eating in the usual manner. In this study, foods are purchased in grocery stores and brought into the laboratory where scientists prepare them by washing, trimming, and cooking (if the food is not consumed raw) in the same manner as they would be in a home or a restaurant. They are then analyzed for pesticide residues and the average daily intakes calculated. These studies have indicated that the residues detected are within the WHO proposed acceptable daily intakes. In Table I, the average daily intake of some pesticide residues for the period 1969-78 are compared. Note the reduction in levels of organochlorine pesticides (e.g. BHC, DDT and dieldrin) which has occurred between 1969 and 1978.

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Table I
Comparison of Average Daily Intake of Pesticide Residues 1969 to 1978

Pesticide	Daily Intake (µg/person)							WHO ADI µg/50kg person
	1969	1970	1971	1972	1973	1974	Apr. 1976-Jan. 1978	
BHC (total)	2.49	2.19	3.46	3.34	2.29	0.92	0.60	500 (lindane)
DDT	18.92	7.43	11.46	4.76	4.10	1.65	0.80	250
Dieldrin	4.02	1.15	2.29	1.50	1.80	0.67	0.15	5
Endosulfan	0.44	0.59	0.35	1.06	1.54	0.30	0.50	375
Diazinon	--	--	1.76	2.19	0.16	--	0.10	100
Malathion	--	2.11	2.96	0.74	0.68	0.02	1.09	1000
Captan	--	1.71	--	--	--	--	0.27	5000

Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"Le contrôle des résidus de pesticides dans les aliments"

Cat. No.: H49-46/12-1990E
ISBN: 0-662-17430-5

Dispatch No. 53

Sweeteners from A to X

Since prehistoric times, humans have sought sweet-tasting substances. Probably the earliest authentic reference to honey and sugar is on a birchbark scroll, dated about 375 A.D., found in the ruins of a Buddhist temple.

Today, the human desire for sweet foods is complicated by a growing desire to reduce energy intake in the diet. There is concern that excess consumption of sugar (sucrose - 16 kilojoules (kJ) per gram) may be detrimental to health. As a result, a variety of alternative sweetening agents - from aspartame to xylitol - have been developed. Now, there are hydrolyzed and concentrated sweeteners such as fructose and corn syrup as well as artificial ones such as the salts of cyclamate and saccharin. Some of these are used by consumers as table-top sweeteners or as sweetening agents in food preparation; others are used primarily as additives by food processors.

All of these sweeteners are regulated by the Health Protection Branch of Health and Welfare Canada. Aspartame, mannitol, sorbitol, thaumatin and xylitol are permitted as food additives in the Food and Drug Regulations. Cyclamates and saccharin are listed separately in their own section since they are no longer permitted as food additives.

Fructose syrups because they are converted from glucose, fall under the standard for glucose and glucose syrups.

Basically, sweeteners are classified as either - *nutritive*, those which are metabolized by animal and human tissues and thus yield energy now measured in kilojoules; and *non-nutritive*, those which do not provide energy.

Introduction

Our society is conditioned to refer to sweeteners as being natural or artificial. Perhaps it is more appropriate to refer to them as nutritive or non-nutritive. The common nutritive sweeteners are controlled in Canada as food ingredients and several standards for such sweeteners appear in Division 18 of the Canadian Food and Drug Regulations. Examples of nutritive sweeteners are: sugar (sucrose), dextrose (i.e. pure glucose), glucose or glucose solids/syrups (i.e. from incomplete hydrolysis of starch), fructose, lactose, etc. Some other nutritive sweeteners, namely, sorbitol, mannitol, and xylitol, are regulated as food additives. Polyols such as sorbitol have slower absorption rates than sucrose and glucose and do not produce any significant changes in blood glucose concentration.

Still other nutritive sweeteners, such as aspartame and thaumatin, also considered to be food additives, have such intense sweetness that they can be used at extremely low use levels and thus, for practical purposes, do not contribute significantly to the caloric value of foods in which they are used. Non-nutritive sweeteners, such as cyclamates and saccharin, are not only intense sweeteners, but have no caloric value. However, these latter two are not permitted to be used as food additives in Canada but are available as table-top sweeteners for an individual's own use.

Nutritive Sweeteners

Aspartame

Aspartame provides energy (16 kJ/g) although it is not a carbohydrate. Aspartame is a synthetic sweetener composed of two amino acids, aspartic acid and phenylalanine, which combine to form a dipeptide which is subsequently methylated to a methyl ester. This white, odourless, crystalline powder is considered a nutritive sweetener since its major components are two naturally occurring amino acids - the "building blocks" of proteins, and are metabolized by the body the same way as other proteins in foods. Because aspartame is 180-200 times sweeter than sucrose, only very small amounts are used for sweetening and thus it provides less energy than sucrose.

Unlike sucrose, aspartame breaks down and loses its sweetness when used in baking or other applications requiring high temperatures or acidity. Therefore, its commercial use is limited.

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Accordingly, the Food Regulations permit aspartame as a sweetener and flavour enhancer only in certain foods (Figure 1). The maximum level of use is specified except for table-top sweeteners. In this case, the level "Good Manufacturing Practice" (GMP) is designated. GMP is defined as the least amount of additive needed to accomplish the specific purpose for which that additive is listed. This does not imply unrestricted usage, but rather usage based on technical needs.

Aspartame may also be used in drugs and cosmetics providing that adequate evidence of product stability is available prior to sale.

The safety data on aspartame has been extensively studied by the Health Protection Branch and by international agencies, such as the Food and Agriculture Organization/World Health Organization Joint Expert Committee on Food Additives. The Branch concurs with the Joint Committee's estimate of an acceptable daily intake of 40 mg/kg of body weight. This means an individual could consume up to 40 mg of aspartame for each kilogram of his/her body weight daily over a lifetime without harm. For example, a typical 280 mL can of soft drink may contain 100-150 mg of aspartame and a 65 kg adult's acceptable daily intake (ADI) is 2600 mg. Thus, consumption of even several cans of soft drink would result in an intake of aspartame much less than the ADI.

Aspartame is not known to cause any harmful effects for most individuals. However, there are about 250 Canadians who suffer from a hereditary disease known as phenylketonuria and who must control their intake of phenylalanine, one of the two amino acids in aspartame. Label statements ensure that they are made aware of its presence in foods containing aspartame. In addition, for carbohydrate-reduced diets, labels must also state amount of calories, protein, carbohydrate, aspartame and fat per 100 mL or 100 g.

The Health Protection Branch has received a limited number of complaints of adverse reactions to this and other food additives. Verification of reactions to food ingredients and food additives is always difficult, particularly when not diagnosed by physicians specializing in food allergies. The Branch is closely monitoring such complaints. Current labelling requirements for food additives allow those who wish to avoid any specific substances to do so.

Corn (glucose) syrups and corn sugars (dextrose)

In 1811, when France was cut off from sugar supplies by a British blockade, Napoleon offered a prize for the development of a new sweetening agent. As a result, it was found that starch could be hydrolyzed to produce corn sugar, glucose and corn syrups. In the manufacture of these sweeteners, cleaned corn is steeped in water and milled. The milling process separates the germ from the starch, gluten, hulls and grits. The starch is then separated by washing and may be converted to corn syrup by continuous acid hydrolysis or enzymes. Glucose syrups are refined using ion-exchange resins to remove minerals and salts. In the manufacture of dextrose, enzymes are used to liquify and hydrolyze the starch as completely as possible, the latter process being known as saccharification. Crystalline dextrose is then obtained from this corn sugar syrup.

High Fructose Syrups

In recent years, high fructose corn syrups and high fructose syrups have resulted from the use of an enzyme (glucose isomerase) which converts glucose into fructose.

A high fructose syrup consists of about 55 percent fructose and has a sweetness equal to or slightly higher than sucrose. It can economically be used to replace sucrose in practically every food sector, including soft drinks. An ultra-high fructose syrup, containing 90 percent fructose is also available. It has a relative sweetness of 1.2-1.7 times that of sucrose, and thus is of interest in the production of reduced-energy foods and beverages.

For diabetics, high fructose syrups have been promoted as substitute sweeteners. Unlike sucrose and glucose which cause quick changes in blood glucose concentration and thereby disrupt the metabolic control of a diabetic, these high fructose syrups are absorbed more slowly and cause smaller changes in the blood glucose concentration. They travel mainly to the liver and can be utilized there without the need for insulin. However, for other tissues to make use of them for energy production, they must be converted to glucose and the transport of glucose to body tissues is dependent on insulin. Thus, even these sweeteners are ultimately insulin-dependent and are not ideal for diabetics. The chart (Figure 2) explains the physiologic and metabolic impact of these syrups and other carbohydrate sweeteners.

Currently, high fructose syrups are considered to fall under the standard for glucose syrup (B.18.016) of the Food Regulations.

Mannitol and Sorbitol

These nutritive sweeteners occur naturally in small amounts in some fruits and vegetables. Both are sugar alcohols but are only half as sweet as sucrose. Mannitol provides about 8 kJ per gram, sorbitol about 16 kJ/g or the same energy value as sucrose.

Mannitol and sorbitol, along with another sugar alcohol, xylitol, have been promoted as useful sugar substitutes for diabetics. All have much slower absorption rates than sucrose and glucose and somewhat slower rates than high fructose syrups when ingested. They do not produce any significant changes in blood glucose concentration (Figure 2). Like high fructose syrups, they travel mainly to the liver and are ultimately insulin-dependent in the final steps of conversion to glucose. Both mannitol and sorbitol are commonly used as

sweeteners in foods for diabetics, but are not ideal either. Since these sugar alcohols are only half as sweet as sucrose, more must be used to reach the same level of sweetness and therefore more energy is consumed. Depending on individual body weight, mannitol may cause diarrhea and abdominal complaints if more than 20 grams are consumed daily; for sorbitol, it is over 50 grams daily. Aside from these intake figures, the amount consumed per eating occasion is also important. Therefore, those particularly sensitive might consider moderating the amount consumed on any one eating occasion.

Mannitol is permitted to be used in Canada in certain energy-controlled and carbohydrate-reduced foods and in confectionery. Sorbitol is also permitted in confectionery and in "unstandardized foods." The amount in a food is governed by GMP (Figure 1).

Xylitol

Xylitol is a natural constituent of many fruits and vegetables, and is obtained commercially from the wood of birch trees. It is as sweet and provides approximately the same number of kilojoules per gram as sucrose. Unlike some of the nutritive sweeteners, xylitol is one which is not implicated in promoting dental caries (Figure 2). Microflora in the mouth do not convert xylitol into organic acids believed to cause dental decay.

The metabolism of xylitol is very similar to that of sorbitol. International studies indicate that oral use of xylitol by diabetics does not significantly affect metabolic control; however, intravenous injection of large amounts has caused severe side effects. Until further investigations are completed, xylitol is now permitted to be used in Canada only in chewing gum (Figure 1).

Thaumatin (Talin)

Talin is a mixture of three closely related sweet proteins, known as the thaumatins, extracted from the aril (sweet part of the fruit on top of the seeds) of *Thaumatococcus danielli*, a plant widely distributed in the rain forest belt of West Africa. While having the number of calories characteristic of a protein (4.1 cal/g or 1 kJ/g, it is intensely sweet. Its apparent sweetness compared with sugar solutions varies non-linearly with concentration, being 5000 - 8000 times sweeter at very low sugar concentrations to 2500 times sweeter at more practical levels (e.g. 8% sucrose equivalence). Thus, when used as a sweetener or a flavour enhancer at lower levels, it is essentially non-caloric at practical use levels.

Other Nutritive Sweeteners

Another nutritive sweetener that may be used in foods, especially ice cream and other dairy products, is lactose derived from whey. This substance when hydrolyzed is a source of glucose and galactose. Other types of sugar substitutes have been proposed such as the sugar alcohol - maltitol; a synthetic sweetener - neohesperidin dihydrochalcone derived from grapefruit peel, and various hydrogenated glucose syrups. To date, none of these are permitted for use in foods in Canada.

Non-nutritive Sweeteners

The era of the sweetener which does not yield energy when consumed actually started back in 1879 when saccharin was discovered. The various salts of saccharin and cyclamate have been both a boon and a bane to consumers and food processors over the years.

Saccharin

Although saccharin leaves a bitter aftertaste when consumed in high concentration, it is about 300 times sweeter than sucrose and therefore, was used extensively in many foods.

The controversy regarding its safety for human consumption began almost immediately after discovery. In the 1970s, extensive testing by the Canadian Health Protection Branch and in several other countries indicated conclusively that saccharin caused bladder tumours in test animals. The Branch decided that, notwithstanding its usefulness as a dietary aid, the use of saccharin as a food additive could not be condoned. Accordingly, the sale in Canada of foods containing saccharin was prohibited in June 1978. However, for those (e.g. diabetics) who required access to an artificial sweetener, saccharin was made available as a table-top sweetener provided it was sold only in pharmacies and provided it bore a label advising pregnant women to use the sweetener only on the advice of a physician.

Cyclamates

Cyclamates, the salts of cyclamic acid, are another non-nutritive sweetener. They are approximately 30 to 50 times as sweet as sucrose.

Cyclamates do not yield energy because they are not metabolized by the body. Some cyclamates may be converted by the microflora in the gastrointestinal tract to cyclohexylamines, and eliminated principally in the urine. The degree of conversion varies from individual to individual, and from day to day.

Cyclamic acid and its salts are controlled separately under Part E of the Food and Drugs Act and Regulations. Cyclamates have been prohibited from use as food additives since 1969. This decision was based on studies which suggested cyclamates were potential carcinogens. On the basis of subsequent data, the Health Protection Branch concluded that cyclamates are probably not carcinogenic, but that the by-product, cyclohexylamine, caused changes in the reproductive organs of male rats. The current acceptable daily intake of 10 mg per kilogram of body weight would be exceeded if cyclamates were

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permitted for use in foods. Therefore, as of June 1978, the Regulations restricted the availability of cyclamates to use as a table-top sweetener, to be used only on the advice of a physician and as a sweetening agent in drugs. This decision meant that cyclamates could still be sold in food stores and distributed to the public in food service establishments.

Conclusion

Canadian consumers and the food industry have a diverse range of sweeteners - from aspartame to xylitol - currently available to them, and more may be available in the future. However, the apparent and potential drawbacks of nutritive and non-nutritive sweeteners indicate that neither group is a panacea for the public's "sweet tooth." As in many cases, moderation in the use of any sweetening agent is the wisest course.

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Table VIII
Miscellaneous Food Additives

Column I Additive	Column II Permitted in or Upon	Column III Purpose of Use	Column IV Maximum Level of Use
Aspartame	(1) Table-top sweeteners	(1) Sweetener and flavour enhancer	(1) Good Manufacturing Practice
	(2) Breakfast cereals	(2) Sweetener and flavour enhancer	(2) 0.5%
	(3) Beverages; Beverage concentrates; Beverage mixes	(3) Sweetener and flavour enhancer	(3) 0.1% in beverages as consumed
	(4) Desserts; Dessert mixes; Toppings; Topping mixes; Fillings; Filling mixes	(4) Sweetener and flavour enhancer	(4) 0.3% in product as consumed
	(5) Chewing gum; Breath-freshener products	(5) Sweetener and flavour enhancer	(5) 1.0%
Mannitol	(1) Carbohydrate or calorie-reduced foods meeting the requirements of sections B.24.004 and B.24.006	(1) To modify texture; Sweetener	(1) Good Manufacturing Practice
	(2) Confectionery	(2) Release agent; Sweetener	(2) Good Manufacturing Practice
Sorbitol	(1) Confectionery	(1) Release agent; Sweetener	(1) Good Manufacturing Practice
	(2) Marshmallows, shredded coconut	(2) Humectant	(2) Good Manufacturing Practice
	(3) Unstandardized foods	(3) To modify texture; Sweetener	(3) Good Manufacturing Practice
	(4) A blend of prepared fish and prepared (fish) meat	(4) To modify texture	(4) 3.5%
Xylitol	(1) Chewing gum	(1) Sweetener	(1) Good Manufacturing Practice
Thaumatin	(1) Chewing gum; Breath-freshener products	(1) Sweetener and flavour enhancer	(1) 500 ppm

Figure 1. Under Division 16 of the Food and Drugs Act and Regulations, five nutritive sweeteners are permitted for use as miscellaneous food additives.

Sweetener	Principal Metabolism	Impact on Blood Sugar and Insulin Secretion	Intestinal Absorption	Laxative Effect	Dental Aspects	Relative Sweetness
SUCROSE	Hydrolysis to glucose and fructose	Moderately high	Active	No	Cariogenic (reference)	1.00 (reference)
GLUCOSE	Insulin-dependent metabolism in all tissues	High	Active	No	Less Cariogenic	0.5-0.8
FRUCTOSE	80% in liver	Slight	Facilitated (not fully known)	No	Less Cariogenic	1.1-1.7
SORBITOL	Oxidized to fructose	Low	Diffusion	Yes	Slightly Cariogenic	0.4-0.5
XYLITOL	Partial utilization in liver	Low	Diffusion	Moderate	Non-Cariogenic	1.0
MANNITOL	Mainly in liver Metabolized in erythro-cytes	Low	Diffusion	Yes	Slightly Cariogenic	0.4-0.5

Figure 2. Physiologic properties and metabolism of carbohydrate sweeteners. Fructose listed here refers to high fructose syrups.

Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"Les édulcorants - A à X"

Cat. No.: H49-46/1-1990E
ISBN: 0-662-17419-4

Dispatch

No. 57

Meal Replacements in Weight Loss Programs

The appearance of various weight reduction diets and foods for use in weight reduction diets, one after another in quick succession, is testament to the fact that many Canadians believe they are overweight, and want to do something about it. The maintenance of a healthy body weight is promoted as one way of reducing the risk of hypertension and cardiovascular disease, as well as other health problems. People are not always content, however, to make weight loss a long-term goal, and they may look for plans or products which promise "quick and easy" weight loss.

Real weight loss -- that is, the loss of accumulated fat -- cannot occur quickly. A diet is not a two-week meal plan, but a way of life. It is an unfortunate fact that deaths have occurred among people using such products as "diet pills" or "liquid protein" diets. Health professionals must, therefore, be aware of the existence of products for use in weight loss plans, and be alert to the effects they may have on health.

What is a meal replacement?

A meal replacement is a formulated product that is designed to replace or substitute for a meal. There are many different meal replacement products available throughout Canada and new ones appear continuously. They are usually sold as a powder to be mixed with milk or water and to be consumed as a beverage or soup; as a ready-to-serve beverage, or as a bar or biscuit. Some meal replacements feature a specific ingredient such as a herb, or perhaps a mixture of herbs, or bee pollen or aloe vera; these specific ingredients are ***not*** responsible for weight loss, however.

Meal replacements may serve a purpose in weight reduction plans, but it is important to note that these products are not always complete foods. Many lack certain essential ingredients, such as dietary fibre. Consumers should be advised to use these products carefully, and to follow directions for their use.

Nutritional Requirements

Books or articles which describe weight reduction diets or programs are not controlled by legislation in Canada unless the use of a specific food or drug, referred to by brand name, is recommended. Any foods or drugs which are represented or sold for use in a weight reduction diet are subject to the Food and Drugs Act and Regulations, which are administered by the Health Protection Branch of Health and Welfare Canada. Under the Regulations, the only foods which may be represented or sold for use in weight reduction diets are meal replacements and prepackaged meals meeting all the compositional and labelling specifications set out for them in the Regulations.

Energy requirements of meal replacements are specified in the Regulations: meal replacements must contain at least 225 kilocalories per serving. This is much less than people usually eat in a meal, so obviously it is the reduction in the amount of food energy provided, not any specific or exotic ingredient, that causes weight loss. If a meal replacement is intended to substitute for all meals, then the total energy supplied by the product must not be less than 900 kilocalories per day when the product is used on a daily basis.

In addition, when a meal replacement is to be used as a replacement for only some of the day's meals, a sample seven-day menu must be included which incorporates the meal replacement and which provides for an intake of at least 900 kilocalories a day.

These energy requirements were set at what was determined by Health and Welfare Canada to be a safe level, based on the use of meal replacement products in the past.

Products promoted for weight loss have been the subject of some concern. In the late 1970s, there were a number of deaths in the U.S. and one in Canada attributed to the use of liquid protein diets or protein-sparing fasts. One of the features of these diets was the low level of energy, about 150 to 450 kilocalories *a day*. (One slice of white bread has about 80 kilocalories.) At such low levels, there is a significant wasting of lean body tissue, not just fat,

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including depletion of tissue from the heart muscles. People on these diets literally starved to death, and this could happen on any very low energy diet, regardless of its composition. Even if there is adequate protein, a source of carbohydrate, and vitamin and mineral supplementation, the body still needs sufficient energy to function.

Extremely low energy dietary regimes may be used by physicians on occasion to treat severe obesity, but these should be used only under direct medical supervision, often in hospital.

To ensure that meal replacements provide a balanced content of macronutrients, and to prevent the sale of "protein" products or products that are really candy bars with vitamins added, the Food and Drug Regulations specify a minimum and a maximum level of protein, and a maximum fat level. The amount of sugar is restricted to a percentage of the total carbohydrate in the product.

Protein	Between 20 and 40 percent of the energy available from the food should be derived from the protein content.
Fat	No more than 35 percent of the energy available from the food should be derived from the fat content; not less than three percent should be from linoleic acid, an essential fatty acid.
Carbohydrate	Not more than 30 percent of the available carbohydrates in the product should be in the form of sucrose or fructose, except when the meal replacement is a cookie or a biscuit.
Calcium to Phosphorus Ratio	Should be not less than one.
Other Vitamins and Minerals	See Table I. These requirements are based on the levels indicated in the *Recommended Nutrient Intakes for Canadians*, and are sufficient to meet the needs of average healthy people.

Labelling

The Regulations set out requirements for the labelling of meal replacements. The labels must provide complete nutritional information for the product as sold, and for a typical serving when ready-to-serve. In addition, labels must list complete instructions for the use of the meal replacement, and the directions must be such that use of the product will result in an energy intake of at least 900 kilocalories a day.

If the meal replacement is to be used as the sole source of nourishment, directions must state the number of servings of the product required each day. If the product is meant to replace one or two meals a day, there must be a sample seven-day menu plan furnished with it, showing how the meal replacement is to be incorporated into a plan with regular meals. The menu must provide for at least one serving from each of the four food groups each day (milk and other dairy products, meat and alternates, bread and cereal products, fruits and vegetables). Each meal on the plan should contribute no more than 40 percent of the day's energy intake, and the total fat must not exceed 35 percent of the total energy for the day.

If the product is to be mixed with milk, there must be a statement that the nutrient content of the meal replacement when ready-to-serve includes milk.

Labels on meal replacements are not allowed to imply that any vitamin or mineral nutrient supplement is required as part of the weight reducing program. The Regulations require that meal replacements contain sufficient vitamin and mineral nutrients to meet the needs of a normal individual.

It is mandatory as well to include a statement that use of the product as directed may result in a decreased intake of energy which in turn may result in weight loss. This avoids the impression that the meal replacement itself, or some special ingredient in it, is effective in bringing about weight loss.

The Value of Meal Replacements

If used according to directions, meal replacements which meet all the requirements set out by the Food and Drugs Act and Regulations are probably safe for use by healthy adults. People who have a health problem or illness, pregnant women and children should **not** use these products without the express advice of a physician.

Use of meal replacements as part of an energy-reduced diet will result in weight loss. However, there are no data available on the safety of these products when used as the sole source of nourishment over a long period of time, or when they are used repeatedly. It is known that they may lack certain essential dietary components (trace elements, dietary fibre), so prolonged use should be avoided.

The reason that most health professionals and reputable nutritionists frown on the use of these products is that they know that the weight loss that comes as a result of short-term use of diet products or plans is only temporary. A truly effective weight loss program is one which features directions as to physical activity and the modification of eating behaviour. Unless new habits are learned, such as how to choose foods which have a better nutrient to calorie ratio, and eating only as much as one needs, any weight that is lost will be regained as soon as the old eating behaviour returns.

On the positive side, meal replacements do provide an energy-controlled portion of food, and there are reports of successful weight loss on programs which include meal replacements. Long-term success depends on whether or not an individual uses meal replacements as part of a comprehensive weight loss program which includes modification of eating behaviour.

The Review Process

Pre-market clearance of foods, food labels, or written promotional or advertising material is not required under the Food and Drugs Act and Regulations. Only radio and television advertisements for foods must be reviewed and approved prior to use. If a manufacturer submits the formulation for a new product to Health Protection Branch for review and comments, the Branch will review the composition of the product before it goes on the market.

Similarly, the Department of Consumer and Corporate Affairs reviews some product labels before the products are marketed. Neither the Health Protection Branch nor Consumer and Corporate Affairs "approves" food products or promotional material. Government officials comment instead on the acceptability of a product or its label with regard to the Food and Drugs Act and Regulations, when requested to do so by the manufacturer. The Bureau of Nutritional Sciences comments specifically on the nutritional claims made by a product manufacturer, and on the nutritional composition of or ingredients in a product. The onus is on the manufacturer to ensure that the product meets all the requirements set out in the legislation.

Health Protection Branch inspectors periodically collect samples of meal replacements for analysis to check for compliance with the Regulations. However, because there is such a large number of products available, and because many are sold through other than retail outlets, consumers are advised to be cautious when purchasing a meal replacement.

How to Choose a Meal Replacement

A meal replacement is likely to meet the requirements of the Food and Drug Regulations if:

- *it provides at least 225 kilocalories per meal and 900 kilocalories per day whether used alone or with a meal plan;
- *it carries the statement that a reduced energy intake is responsible for weight loss;
- *it specifies the nutrients contained per 100 grams and per serving when prepared according to directions;
- *it makes no claims about extraordinary weight loss (more than one kg a week) or about the effectiveness of certain ingredients such as bee pollen or other substances, or about the ability to prevent or treat disease;
- *it has a menu plan that contains at least one serving from each of the four food groups, each day.

Consumers are further advised to look for products that are to be made up with milk, and to be sure that the meal replacement is intended to replace only one or two meals a day as part of a meal plan that incorporates food.

The Ontario Milk Marketing Board has formulated some excellent guidelines for choosing a diet program. A "Yes" answer is required for all the following questions for a diet to be judged safe and reasonably effective.

Does the Diet ...

1. Include a variety of foods you normally eat and enjoy?
2. Recommend choosing foods each day according to *Canada's Food Guide?*
3. Include a variety of foods from all four food groups (no one food or group is promoted)?
4. Rely on food for essential nutrients (not solely on vitamin or mineral pills or a meal replacement)?
5. Provide for *gradual* weight loss (less than two kg a week)?
6. Allow nutritious snacks?
7. Emphasize portion control?
8. Recommend that a doctor, nutritionist or other health professional be consulted?
9. Recommend increasing physical activity?

It is important to note that while many Canadians may believe themselves to be overweight, this may not in fact be the case. Those planning to go on a program of weight reduction should be advised to consult first with their physician, community health centre and/or a nutritionist for a thorough evaluation of their health, body weight and dietary habits.

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Table I. Vitamin and Mineral Requirements

Vitamins	Minimum per serving	Maximum per serving
Vitamin A	1250 I.U.	2500 I.U.
Vitamin D	25 I.U.	50 I.U.
Vitamin E	3.5 I.U.	7.0 I.U.
Vitamin C	7.5 mg	15 mg
Thiamine	375 mcg	750 mcg
Riboflavin	425 mcg	850 mcg
Niacin	5 mg	10 mg
Vitamin B_6	0.5 mg	1.0 mg
Vitamin B_{12}	0.75 mcg	1.5 mcg
Folic acid	50 mcg	100 mcg
Biotin	10 mcg	20 mcg
d-pantothenic acid	1.25 mg	2.5 mg
Minerals		
Calcium	200 mg	400 mg
Phosphorus	200 mg	400 mg
Iron	3.5 mg	7 mg
Iodine	35 mcg	70 mcg
Magnesium	75 mg	150 mg
Copper	0.5 mg	1.0 mg
Zinc	2.5 mg	5 mg
Potassium	375 mg	-
Manganese	0.65 mg	1.3 mg
Sodium	250 mg	-

Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"Les substituts de repas dans les régimes amaigrissants"

Cat. No.: H49-46/9-1990E
ISBN: 0-662-17427-5

Dispatch No. 59

Analgesics

"What nobler aim can man attain than conquest over human pain?" That is the question asked in a 19th century advertisement for fruit salts. A century ago, all manner of pills, potions, ointments and even mechanical devices were sold as pain relievers and as cures for a variety of problems.

Today, analgesic drugs are still popular with Canadians. In fact, non-narcotic pain relievers sold without prescription represent the largest group of drugs sold in Canada. In 1982, for example, 286 million units of the 325 mg dose form of acetylsalicylic acid (ASA) were sold. Acetaminophen and combinations of acetaminophen or ASA with other pharmaceuticals are also frequently purchased.

We Canadians tend to see the ability to treat our minor aches and pains as a right. It is estimated that over 80 percent of the minor symptoms of illness are treated without medical consultation. The advantages of self-medication are obvious -- treating one's own minor pains is more convenient and less costly to our health care system than seeing a physician for each headache or bout of the "flu" -- but there are disadvantages of self-medication too. Many of the symptoms commonly treated with analgesics may be signs of serious disease, and thus treatment of the symptoms alone may delay diagnosis. In addition, pain relievers can have side effects when taken with alcohol or with other drugs, both prescription and non-prescription.

The responsibility for good health rests with the individual. Although most pain relievers may be purchased without a prescription -- indeed, some are even sold in grocery stores -- analgesics are serious medicine, and consumers bear the responsibility for wise use of these drugs. They should be used only when absolutely necessary. Knowing the facts about analgesics is important for safe and effective use.

Use of Analgesics

There are three common indications for the use of analgesics:

- the relief of minor, temporary aches and pains,
- the reduction of fever,
- the relief of pain and inflammation and certain inflammatory conditions. (Only the salicylates are effective at reducing inflammation, however.)

Usually, minor aches and pains are the result of temporary problems such as fatigue, tensions or anxiety, but they may also be signs of viral illness such as a cold or the "flu". The use of non-prescription analgesics is appropriate for these problems, but consumers should be aware that the use of analgesics for minor pains is meant to be **temporary**: if a symptom persists for more than five days, a physician should be consulted.

Pain may be a symptom of a larger problem, a bacterial infection for example, and not a disease in itself. Consumers who diagnose and treat themselves with analgesics can risk overlooking real illness.

Over-the-counter analgesic preparations are also often used as antipyretics -- that is, to reduce fever. Once again, fever is a sign of a larger problem, usually a viral illness, so consumers should be advised to contact their physician or nurse if a fever persists for more than 24 hours in a child or a few days in an adult, if it is very high (over 40°C or 104°F), or when an infant under the age of 12 months has a fever.

The salicylate group of analgesics has proven useful in relieving the pain of inflammatory conditions such as arthritis, but the use of analgesics for this purpose definitely requires diagnosis by a physician, and strict monitoring of treatment. In addition, analgesics are not sedatives or tranquilizers and are not intended for such use. In spite of reports that ASA in particular is useful in treating some forms of cardiovascular disease, no one should attempt to treat or prevent cardiac disease by taking regular doses of this drug without the express recommendation of a physician.

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External Analgesics

Some pain relievers are not taken by mouth but are applied directly to the skin, and are commonly used to relieve pain in muscles or joints. In fact, when analgesics are used in this way, they act as counter-irritants in that they irritate the skin to produce a sensation of warmth, which results in some relief of pain.

External analgesics include oil of cloves (the principal ingredient of which is eugenol) methyl salicylate, and others. Because of the irritating action of these preparations, external analgesics should **never** be used on children, on burned or injured skin, near the eyes or on mucous membranes or genitalia. People who are sensitive or allergic to salicylates may have a reaction to externally applied salicylates. If a reaction occurs with any of these drugs, their use should be discontinued at once.

Internal Analgesics

Most analgesics which can be taken internally are supplied not only in tablet or capsule form, but also in other oral preparations and in suppositories. Acetaminophen, for example, is supplied in a flavoured liquid, while ASA can be bought in a medicated chewing gum. Both drugs are found as ingredients in many cough and cold preparations.

There are two groups of drugs which act as non-narcotic analgesics: the salicylates and the non-salicylates.

Salicylates

The best known of this group of drugs is acetylsalicylic acid (ASA), but all the salicylates, whether natural or synthetic, work as analgesics, antipyretics and as anti-inflammatory agents. ASA is generally considered to be safe for most people, when used only occasionally and in the recommended doses. It is in fact the most commonly used drug in the analgesic group. ASA is probably present in some form in most medicine cabinets and because it is so common, many people tend to think of ASA as a benign or harmless drug. It isn't: salicylate poisoning is a danger when ASA is used in high doses, and because the drug is so readily available, poisoning is a real danger for young children. Parents, or anyone with young children in their home, should be cautioned to keep ASA and all drugs in tightly closed containers out of the reach of children.

Some people are sensitive or allergic to salicylates. The signs of an allergic reaction include difficulty in breathing or swallowing, or the appearance of hives or a rash.

Salicylates are beneficial for minor problems such as headache, and the aches and fever that come with a viral illness, but these drugs do have a number of side effects. The most common side effect of salicylates is gastric irritation. ASA is an acid, and because it is absorbed through the gastrointestinal tract, there is some irritation, even some minor bleeding, with every dose. For this reason, it is recommended that salicylate pain relievers be taken with milk or water and preferably not on an empty stomach. People who have previously existing gastric conditions such as an ulcer or a tendency to stomach upset or "heartburn" should avoid the use of these drugs.

ASA also has an effect on the clotting time of human blood which means that people who are taking anti-coagulant drugs to prevent the formation of blood clots should avoid ASA or at least ask their physician how much ASA they may take safely.

ASA may precipitate an acute attack of gout in individuals with a history of gout. As well, ASA diminishes the effect of drugs used to treat gout. Therefore, people with a history of gout should avoid taking ASA, whether or not they are taking drugs to treat gout.

In general, drugs should not be mixed without consulting a physician or pharmacist, even when the drugs are sold over-the-counter and without prescription. ASA can interact with a number of other drugs; for example, ASA can enhance the action of some oral hypoglycemics, taken by some diabetics to control blood sugar, and thus may result in low blood sugar. ASA increases the action of some anticoagulant drugs and diminishes the effect of drugs. It may increase gastric irritation when taken with some drugs used to treat arthritis and, if used in large doses over a long period of time, may contribute to iron deficiency anemia.

ASA should not be taken with alcohol. Both substances cause gastric irritation and when taken together, exaggerate this effect.

Children and teenagers should not use products containing ASA before a physician is consulted about Reye's Syndrome, a rare but serious illness.

ASA and Pregnancy

In general, the use of any drug should be avoided during pregnancy. The occasional use of ASA in the recommended doses is not likely to cause any harm to the unborn baby. But taking ASA on a regular basis should be avoided during the first three months of pregnancy when the fetus is being formed, and during the last three months when it may alter clotting time and lead to excessive bleeding in either the baby or the mother at birth.

Combinations

The salicylates may be sold as single-ingredient drug preparations or they may be combined with other drugs such as codeine or caffeine. The analgesic effect of caffeine when used as an adjuvant is still being investigated. ASA is also sold in combination with certain buffering agents which are thought to help decrease gastric distress.

ASA and other salicylates are also often included as an ingredient in many cold remedies and in some preparations for the relief of stomach upset. It is wise to check the

ingredients on the labels on all medications to avoid getting a larger than recommended dose of salicylate, which may happen if two drugs are taken together.

Combinations of salicylates and acetaminophen, or other analgesics, are not permitted in non-prescription medicines. They are no more effective than either drug alone and may cause serious kidney damage.

Non-salicylates

The most popular non-salicylate, non-narcotic analgesic is acetaminophen, which belongs to a group of drugs called para-aminophenols. These drugs, like the salicylates, have analgesic and antipyretic properties, but they have no effect on inflammation and are not used to relieve symptoms of inflammatory disease like arthritis.

Acetaminophen seems to have fewer side effects than does ASA. It does not, for example, tend to irritate the stomach, it does not affect clotting time, and fewer people seem to be sensitive or allergic to it. On the other hand, there is a high potential for liver damage when acetaminophen is taken in high doses or when combined with certain other drugs which are toxic to the liver. Chronic alcohol consumption increases the liver damage that may be produced by excessive doses of acetaminophen. There is no danger, though, when the drug is taken only occasionally and in the recommended doses. However, persons with liver disease might experience adverse effects from acetaminophen.

Acetaminophen is available in tablets, capsules and suppositories as are the salicylate analgesics. Because it is also available in liquid form, the drug is popular for use in very young children.

Analgesics and Children

Fever in children is a frequent cause of concern among parents. Generally, the best course is to control fever when a child becomes ill with a virus infection. Once a child's temperature rises above 38.5°C or 102°F rectally, or 38°C/101°F orally (and parents should use a thermometer to measure temperature accurately), treatment of the fever should be started immediately.

- Give the child plenty of fluids to drink, preferably clear fluids such as water, diluted apple juice or flat ginger ale.
- Remove excess covers and clothing.
- Keep the room temperature at 18°C or 66°F.
- Sponge the child with tepid or lukewarm water -- NEVER with alcohol.

If the fever does not respond to these measures within 24 hours, OR if it rises above 40°C or 104°F, a physician or nurse should be contacted as soon as possible. If the child's temperature is high, antipyretic drugs may be given, in the recommended dosage, once every four hours. Some young children are prone to develop febrile convulsions when their body temperature rises suddenly, so temperature should be checked often. Infants under the age of 12 months should never be given any drugs without medical advice.

Children and teenagers should not use products containing ASA before a physician is consulted about Reye's Syndrome, a rare but serious illness.

ASA should be avoided by children with influenza or chicken pox. Some reports have suggested an increased risk of children with these illnesses developing Reye's Syndrome, a very infrequent but serious complication of viral infections, when treated with ASA.

A number of factors influence the way in which drugs are metabolized and absorbed in children, so dosages of analgesics for children are different from those recommended for adults. When any drug is to be given to a child, parents or guardians should read the label carefully and follow a physician's recommendations.

Analgesics and Breastfeeding

Many drugs will pass through to the breast milk when taken by a breastfeeding woman and are thus ingested by the baby. For this reason, nursing mothers should take drugs only when necessary and only with the advice of their physician. Both ASA and acetaminophen are secreted into breast milk. Although usually the amount of any drug taken by the mother is present in the breast milk only in very low doses, older infants consume upwards of 750 mL of milk a day, which means they may ingest pharmacologically active levels of a drug.

Regulation of Analgesics

The manufacture and sale of non-prescription drugs in Canada is regulated under the Food and Drugs Act and Regulations. The purpose of this legislation is to ensure that drugs on the Canadian market are safe when used under reasonable conditions, and are effective in treating the conditions for which they are indicated.

A review of all non-prescription drugs was initiated in 1977 by the Health Protection Branch with the goal of providing a framework for the sale and appropriate use of these drugs. Various categories of drugs, including analgesics, have been examined with regard to acceptable advertising claims, reasonable package sizes, appropriate labelling, elimination of outmoded drugs, and the length of time for which self-medication is considered safe.

Major changes have been made to the regulations pertaining to analgesics, and the new regulations are now in effect.

- Dosage levels for acetaminophen and all salicylate-based products (e.g. ASA) will be available in standard dose form of 325 mg per tablet or capsule. Two tablets will provide most people with relief from the level of pain that is considered appropriate for self-medication.
- Higher strength acetaminophen and salicylate products will still be available for those people who require stronger non-prescription medication occasionally. Advertising for these products is restricted to statements about name, price and quantity, as for prescription drugs.
- The standard dose for children of acetaminophen, ASA and sodium salicylate is 80 mg per solid dose form when administered by calibrated dropper. (Doses of 160 per 5 mL or 160 per mL when administered by calibrated dropper are currently being evaluated and may be available in the future. For liquid formulations of acetaminophen, the standard dosages are 80 mg per 5 mL or 80 mg per mL when administered by calibrated dropper.
- All non-prescription analgesic products will carry statements on the label cautioning consumers not to use the product continuously for more than five days, or to exceed the recommended dose without first contacting a physician.
- Acetanilid, phenacetin, antipyrine, and quinine as analgesics, have been made prescription drugs. In addition, the effectiveness of salicylamide has not been demonstrated and salicylamide is no longer available as a non-prescription drug.
- Buffered salicylates are permitted as non-prescription drugs; however, their representation as antacids is misleading and is considered unacceptable advertising.
- The use of caffeine as an ingredient in analgesic preparations has been questioned. Studies are in progress to determine the effectiveness of caffeine in analgesic preparations and will be reviewed by the Health Protection Branch.

Summary

All drugs are really two-edged swords: they can be beneficial but they may also be harmful, especially when used improperly or inappropriately. To ensure safety in the use of non-prescription analgesics, consumers should always read the label on any drug preparation and follow the directions for dosage and use. All proprietary analgesics are intended for occasional use to alleviate temporary problems; if a symptom persists, the individual should contact his or her family doctor or local community health centre.

Pain may be a sign of a larger and perhaps serious problem, for which professional diagnosis and treatment may be required.

A pharmacist may also be consulted for information concerning the use of analgesics.

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Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"Les analgésiques"

Cat. No. H49-46/5-1990E
ISBN 0-662-17423-2

Dispatch No. 60

Point-of-use Water Treatment Devices

Canadians are becoming concerned about the quality of their drinking water due to an increased awareness of environmental pollution and of the limitations of water treatment processes. Safe drinking water is essential to health. Unfortunately, many cities are located close to sources of pollution and thus some Canadians fear for the chemical quality and safety of their drinking water.

Chemically "pure" water does not exist in nature; water is known as the universal solvent and always contains a variety of chemicals and minerals. The presence of these substances does not mean that water is not "safe," but to many people, the mere mention of chemicals in water brings to mind thoughts of pollution, disease and cancer.

A visible manifestation of the public's concern is the phenomenal rise in the sale of point-of-use water treatment devices. Current sales are at about 100 000 units annually, with a retail value of $20 million.

About 70% of the treatment devices sold use activated carbon filters. Health professionals are concerned because bacteria tend to grow in carbon filters over time, which means that some water treatment devices may actually contaminate the water they are intended to treat.

Health Protection Branch

It is due to the burgeoning use and concomitant questions about safety and effectiveness of water treatment devices, that the Environmental Health Directorate of the Health Protection Branch, Health and Welfare Canada, has established a program to evaluate these devices. At present, such devices are not subject to regulation and there are no accepted performance standards. In general, it is considered essential that the water treated by point-of-use devices meet the quality specified in the *Guidelines for Canadian Drinking Water Quality*.

In Canada, provision and monitoring of most drinking water is a provincial responsibility. However, the general provisions of the federal Health and Welfare Act (Section 5) provide the basis for any research or regulatory activities carried out. For example, Canada's guidelines on drinking water quality have recently been revised, to take into account new scientific data and concerns since the last revision.

Water treatment devices can be classified into two groups: those used for the disinfection of water, and those which remove taste, odour and chemicals.

I. Disinfection

Disinfection of water may be required on a continuous basis or for occasional use when microbial contamination of water may have occurred. For occasional or short-term use, there are several simple methods of disinfecting water which require no devices:

* boiling water for one minute will kill most common pathogens, but boiling for at least five minutes will ensure disinfection;
* household bleach, which contains four to five percent sodium hypochlorite, will disinfect water when at least five drops are added to four litres of water and left to stand for 30 minutes;
* water purification tablets which release chlorine or iodine may be purchased and are especially useful for travellers when used according to manufacturers' directions.

Where disinfection of water must be carried out on a continuous basis due to dubious quality of raw water or the possibility of periodic contamination, a point-of-use device may be more practical than the short-term methods described. Efficacy, reliability, cost and maintenance requirements are all important considerations; for a review of the systems used successfully in Canada, see Table 1.

For disinfection of water serving a whole house, chlorinators and ultraviolet light devices are the most practical. Chlorine generally kills disease-causing organisms and requires short to moderate contact time, depending on the amount of organic matter present. Chlorinators are widely used in large municipal systems as well as on small private systems such as wells.

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Ultraviolet devices are also effective against pathogens, add nothing to water, produce no taste or odour, and in clean water require only a few seconds' exposure to be effective. The drawback is that they do not ensure safety of water beyond the point of application so that flushing of the system is recommended after periods of non-use.

Ceramic candles and iodinators handle smaller amounts of water and are useful when the water from just one tap is to be treated for drinking and cooking. Care should be taken in these cases to avoid ingestion of untreated water by using water from other taps for brushing teeth, etc. Ceramic cartridge filters consist of a cylindrical element or "candle" with a hollow centre. Water is filtered from the outside of the device to the inside, and bacteria and particulate matter are filtered through the candle pores. The candle usually contains silver which helps prevent bacterial growth into the centre. Occasional abrasion of the candle surface is required to remove material and to restore normal flow rate.

Iodinators are relatively simple devices which disinfect water by dosing an iodine solution into the main water stream. Iodine should not be used, however, for long-term continuous disinfection because the element is physiologically active and an excessive intake may be harmful.

Distillation and ozonation are suitable for use where electric power is available and there is enough space to house the apparatus. Water is boiled in a still and the vapour is condensed and collected. The process removes most metals and inorganic contaminants but it may not remove all organic materials. Thus, stills may be combined with carbon filtration to achieve more complete water treatment. Ozonators produce small quantities of ozone, a strong oxidizing gas, which is effective in killing pathogens in a short exposure time, while producing no taste or odour. The process is dependent on good mixing of ozone with the water however, and the residual effect is very short-lived.

II. Removal of Chemical Contaminants

It is not generally appreciated that much of Canada's drinking water is highly processed. In fact, more than a million tons of chemicals are added each year to drinking water. Despite the fact that most municipally treated water is adequately processed, many Canadians fear the presence of harmful contaminants. It is true, too, that the chlorination of drinking water may produce low levels of halogenated by-products some of which are suspected carcinogens. This fact has spurred interest in alternative methods of water treatment. In most cases, no health risk is present, but certain aspects of the water supply in some areas may not be esthetically appealing.

Water Softeners

A number of devices are available for removing chemicals and improving the quality of water (see Table 2). The most common type is the water softener; its main function is to remove calcium and magnesium from "hard" water. While softening water makes it more suitable for washing and prevents deposits in appliances and pipes, the water is not generally recommended for drinking or cooking due to its increased sodium content, decreased essential mineral content and the potential of bacterial growth.

Carbon Filters

Carbon filters (powdered, granular or pressed block) are more effective in removing organic chemicals from water than inorganic; they are often used to remove taste, odour, chlorine and hydrogen sulphide and may be combined with other treatment processes. Nevertheless some pressed carbon block filters will reduce levels of heavy metals in water.

The principal disadvantage of activated carbon filters (including those which contain silver) is their ability to foster bacterial growth on the trapped organic substances, and to release those bacteria into the water. Some carbon filters contain membrane filters to retain the bacteria, but these membranes will not remove all microorganisms. It is imperative then that all activated carbon filters be used only on water which meets guidelines for microbiological safety, and that these filters be flushed before use.

Another disadvantage is the variability in removing organic contaminants from water. Research has indicated as well that the efficiency of these filters with regard to some contaminants decreases with use.

The risk of using activated carbon filters can be lowered by following these steps:

* Use only with microbiologically safe water.
* Flush for at least 30 seconds before use.
* Change filters frequently.
* Follow manufacturers' advice for installation and service.

Others

As already mentioned, both distillation and reverse osmosis processes remove chemical contaminants such as heavy metals, but they are not totally effective against organic contaminants. In addition, reverse osmosis membranes are not highly efficient at water pressures normally encountered.

Storage of Water

Ideally, treated water should be consumed immediately after treatment to prevent deterioration. Some types of bacteria can grow in almost any water, especially at warm temperatures. If water is not to be used right away, it may be stored for no more than a few days in the refrigerator. Home treatment devices should be flushed for 30 seconds after any period of non-use. Water that is stored in tanks at room temperatures -- in boats and campers, for example -- poses a special problem. Storage tanks should be cleaned and disinfected periodically, and the water replaced; disinfection of the water may be necessary to ensure safety.

Choosing a Water Treatment Device

Advertising claims for a given point-of-use water treatment device are an important factor in the selection of a device by most consumers. For this reason, it is essential that claims accurately represent the performance of the product. Tests of such a device carried out for the manufacturer by reputable laboratories can be useful in evaluating the claims made for it. Often, however, these tests may be incomplete or insufficiently described to be useful. If there is any doubt about the effectiveness of the device, advice should be sought from provincial health or environment officials who are the experts in this field.

In conclusion, it is important for health professionals advising consumers about the safety and effectiveness of point-of-use water treatment devices to understand the following points:

* The specific contaminant in the water supply must be known in order to choose the most effective treatment process.
* Most point-of-use devices are intended for use only on municipally treated water, not "raw" untreated water.
* Activated carbon filters can pose a significant risk to health if installed or used improperly.

Health professionals should enquire about the use of such devices when seeing clients or patients who exhibit symptoms of gastroenteritis.

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Canadian Water and Wastewater Association
24 Clarence St. West
Ottawa, Ontario
K1N 5P3

Cost: $25.00

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80-EHD-54 - Assessing the effectiveness of small filtration systems for point-of-use disinfection of drinking water supplies.

Available from:

Environmental Health Directorate
Health Protection Branch
Ottawa, Ontario
K1A 0L2

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Available from:

Canadian Government Publishing Centre
Supply and Services Canada
Publicity and Promotion Section
Ottawa, Ontario
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Published by authority of the Minister of National Health and Welfare

Également disponible en français sous le titre
"Dispositifs de traitement de l'eau au point d'utilisation"

Cat. No.: H49-46/8-1990E
ISBN: 0-662-17426-7

Table 1. Devices for Disinfection of Water

Type	Advantages	Limitations	Special Requirements
Ceramic Candles	Inexpensive, simple	May not be effective against viruses	
Chlorination	Proven technology	May require additional filters to remove protozoan cysts	Residual test kit, electricity
Distillation	Effective against all pathogens	Batch system - water may not be available when required	Electricity
Iodination	Inexpensive	May require additional filters to remove cysts. Possible physiological effects of iodine	Residual test kit
Ozonation	Low operating cost	May require additional filters to remove cysts. Iron, sulphur and manganese must not be excessive	Electricity
Ultraviolet Light	Uses no chemicals	May require additional filters to remove cysts. May be only partially effective if water is turbid	Electricity, UV monitor

Table 2. Devices for Taste, Odour and Chemical Removal

Type	Advantages	Limitations	Special Requirements
Activated Carbon	Removes taste, odour, organics, chlorine, low levels of hydrogen sulphide	Should be used on microbiologically safe water	Cartridges should be changed regularly
Chlorination	Iron, manganese, hydrogen sulphide removal		Electricity, filter to remove precipitates
Distillation	Removes inorganic salts, some organic chemicals, particles, hydrogen sulphide	May concentrate some organic chemicals	Electricity
Green Sand Filters	Iron, manganese, hydrogen sulphide removal	May clog or reduce effectiveness due to bacterial growth	Backwash and regenerate regularly, replace media
Particulate Filters	Turbidity, particle removal		
Reverse Osmosis	Inorganic salts removal	Susceptible to clogging	Adequate water pressure, flush
Softeners	Hardness (calcium, magnesium) removal	Elevates sodium content; possible bacteria growth	Usually require electricity